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Double bag or Y-set versus standard transfer systems for continuous ambulatory peritoneal dialysis in end-stage kidney disease (Review)

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[Intervention Review]

Double bag or Y-set versus standard transfer systems for continuous ambulatory peritoneal dialysis in end-stage kidney disease

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ABSTRACT

Background

Peritonitis is the most frequent serious complication of continuous ambulatory peritoneal dialysis (CAPD). It has a major influence on the number of patients switching from CAPD to haemodialysis and has probably restricted the wider acceptance and uptake of CAPD as an alternative mode of dialysis.

This is an update of a review first published in 2000.

Objectives

This systematic review sought to determine if modifications of the transfer set (Y-set or double bag systems) used in CAPD exchanges are associated with a reduction in peritonitis and an improvement in other relevant outcomes.

Search methods

We searched the Cochrane Renal Group's Specialised Register through contact with the Trials Search Co-ordinator. Studies contained in the Specialised Register are identified through search strategies specifically designed for CENTRAL, MEDLINE and EMBASE. Date of last search: 22 October 2013.

Selection criteria

Randomised controlled trials (RCTs) or quasi-RCTs comparing double bag, Y-set and standard peritoneal dialysis (PD) exchange systems in patients with end-stage kidney disease.

Data collection and analysis

Data were abstracted by a single investigator onto a standard form and analysed by Review Manager. Analysis was by a random effects model and results were expressed as risk ratio (RR) or mean difference (MD) with 95% confidence intervals (CI).

Main results

Twelve eligible trials with a total of 991 randomised patients were identified. Despite the large total number of patients, few trials covered the same interventions, small numbers of patients were enrolled in each trial and the methodological quality was suboptimal. Y-set and

twin-bag systems were superior to conventional spike systems (7 trials, 485 patients, RR 0.64, 95% CI 0.53 to 0.77) in preventing peritonitis in PD.

Authors' conclusions

Disconnect systems should be the preferred exchange systems in CAPD.

PLAIN LANGUAGE SUMMARY

Y-set and double bag systems offer the most protection against peritonitis during continuous ambulatory peritoneal dialysis (CAPD)

People with advanced kidney disease may be treated with CAPD where a catheter is permanently inserted into the peritoneum (lining around abdominal contents) through the abdominal wall and sterile fluid is drained in and out a few times each day. The most common serious complication is infection of the peritoneum - peritonitis. This may be caused by bacteria accidentally being transferred from the catheter. This review of trials compared three types of connecting systems (used to connect the bags and the catheter) and found the Y-set and double bag exchange systems are the most effective in preventing peritonitis.

BACKGROUND

Continuous ambulatory peritoneal dialysis (CAPD) has been used as an alternative to haemodialysis for patients with end-stage renal disease (ESRD) since 1976 (Popovich 1976). It may be used as the first choice dialysis therapy and in a number of countries including the United Kingdom a significant proportion of the ESRD population are treated by this modality in preference to chronic haemodialysis. A peritoneal dialysis (PD) exchange involves draining CAPD dialysate solution into and out of the peritoneal cavity using a permanently implanted PD catheter and a transfer or connection system. Peritonitis is the most common serious complication of PD and is the leading cause of technique failure requiring a switch to haemodialysis (CANUSA 1996). Undertaking a PD exchange is one of the key points during CAPD when micro-organisms can be inadvertently transferred via the lumen of the peritoneal catheter into the peritoneal space (intraluminal route) causing peritonitis. The CAPD transfer system used may therefore have an important bearing on both the incidence of peritonitis and CAPD technique failure.

There are three main types of catheter connecting systems. In the "standard" or straight connecting system the catheter is connected to the dialysate solution bag using a straight piece of tubing and a "spike" or a luer lock device. At each exchange a new connection is made and the bag is drained. The empty bag is rolled up and remains attached until the next exchange when the process is repeated. The second type of transfer system is the Y-set in which the patient disconnects (disconnect system) from the bags between exchanges. When a new exchange is due a Y-connection with one limb connected to an empty bag and one to a bag containing fresh dialysate is used (Buoncristiani 1980; Buoncristiani 1993; Buoncristiani 1996). During an exchange the peritoneal dialysate is first drained from the peritoneal cavity into the empty bag. Before introducing the fresh dialysis solution into the peritoneal cavity the Y-connecting system is first flushed with fresh dialysis solution and drained into the drainage bag. This allows any bacteria to be flushed into the spent fluid. The fresh fluid is then introduced into the peritoneal cavity and the Y-connector is disconnected from the CAPD catheter. The early Y-set technique, in addition, flushed the system with a disinfectant, a hypochlorite, during each exchange (Buoncristiani 1983). The third system, the double bag (twin bag) system, is a further development of the Y-set disconnect systems. With this system the connection with the fresh dialysis solution bag is already made and the patient has to perform one less connection procedure (Balteau 1991; Bazzato 1980). It has been suggested that use of the Y-set transfer or double bag systems will lead to a reduced frequency of CAPD peritonitis (Buoncristiani 1983) and some (Golper 1996; Port 1992) observational studies have indicated an association between use of the standard connect system and a significantly increased risk of peritonitis. At present a considerable proportion of CAPD patients, continue to use the standard system. Other techniques, such as the Ultraviolet Germicidal System (Churchill 1991; Nolph 1985), in-line bacteriological filters (Churchill 1991; Slingeneyer 1983) and heat sterilisation (Churchill 1991; Durand 1995) have been developed and used in an attempt to reduce peritonitis rates; they were not considered as part of this review.

OBJECTIVES

To evaluate the evidence that supports the use of the Y-set (and modifications) and double bag systems for the prevention of peritonitis in PD patients.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) and quasi-RCTs investigating the effect of the Y-set or double-bag systems to prevent PD peritonitis.

Types of participants

Adult and paediatric patients undergoing PD treatment.

Types of interventions

1. Double bag (experimental group) and/or Y-set (experimental group) versus standard CAPD exchange systems (control group).
2. Double bag (experimental group) versus Y-set (control group).

We included studies where disinfectant had or had not been used to flush and/or to be retained in the elements of the Y-set system. For either the Y-set or double bag systems the sequence of the exchanges could vary:

1. drain/flush/fill or
2. flush/drain/fill.

Types of outcome measures

1. Number of patients experiencing peritonitis and peritonitis rate (number of episodes per patient months on treatment) (primary outcome)
2. Number of patients experiencing exit-site/tunnel infections and exit-site/tunnel infection rate (number of episodes per patient months on treatment)
3. Number of patients in whom CAPD catheters were removed
4. Number of patients switching to haemodialysis
5. Number of patients hospitalised and average number of days of hospitalisation
6. Measures of quality of life and patient preference
7. All-cause mortality

Search methods for identification of studies

We searched the Cochrane Renal Group's Specialised Register on 23 October 2013 through contact with the Trials' Search Co-ordinator using search terms relevant to this review.

The Cochrane Renal Group's Specialised Register contains studies identified from several sources:

1. Monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL)
2. Weekly searches of MEDLINE OVID SP
3. Handsearching of renal-related journals and the proceedings of major renal conferences
4. Searching of the current year of EMBASE OVID SP

5. Weekly current awareness alerts for selected renal journals
6. Searches of the International Clinical Trials Register (ICTRP) Search Portal and ClinicalTrials.gov.

Details of these strategies, as well as a list of handsearched journals, conference proceedings and current awareness alerts, are available in the Specialised Register section of information about the Cochrane Renal Group. See Appendix 1 for search terms used in strategies for this review.

For search strategies used in our previous review please see Daly 2000.

Data collection and analysis

The full-text of each relevant identified study were assessed independently by two assessors for subject relevance and methodological quality using a standard form. Details concerning method of random allocation, blinding, description of withdrawals and dropouts, and whether data were analysed on an intention to treat basis were noted.

Data abstraction

Data on predetermined outcome measures were abstracted from included studies using a standard form, by a single assessor and data-entry on REVIEW MANAGER 4.2.3 was performed. All data were independently checked from the original papers by a second investigator. A third investigator performed data abstraction and requested additional unpublished or unclear information from the authors of all included trials at the time of updating the present review.

Study quality

The quality of included studies was assessed by two independent investigators without blinding to authorship or journal using the checklist developed by the Cochrane Renal Group. Discrepancies were resolved by discussion with a third investigator. The quality items assessed were allocation concealment, blinding of investigators, participants and outcome assessors, intention-to-treat analysis, and the completeness to follow-up.

Quality checklist

Allocation concealment

- Adequate (A): Randomisation method described that would not allow investigator/participant to know or influence intervention group before eligible participant entered in the study
- Unclear (B): Randomisation stated but no information on method used is available
- Inadequate (C): Method of randomisation used such as alternate medical record numbers or unsealed envelopes; any information in the study that indicated that investigators or participants could influence intervention group

Blinding

- Blinding of investigators: Yes/no/not stated
- Blinding of participants: Yes/no/not stated
- Blinding of outcome assessor: Yes/no/not stated
- Blinding of data analysis: Yes/no/not stated

The above are considered not blinded if the treatment group can be identified in > 20% of participants because of the side effects of treatment.

Intention-to-treat analysis

- Yes: Specifically reported by authors that intention-to-treat analysis was undertaken and this was confirmed on study assessment.
- Yes: not specifically stated but confirmed on study assessment
- No: Not reported and lack of intention-to-treat analysis confirmed on study assessment (Patients who were randomised were not included in the analysis because they did not receive the study intervention, they withdrew from the study or were not included because of protocol violation).
- No: Stated, but not confirmed upon study assessment
- Not stated

Completeness to follow-up

Percent of participants excluded or lost to follow-up.

Statistical assessment

Data from individual trials were analysed using the risk ratio (RR) measure and its 95% confidence intervals (CI) for dichotomous outcomes and the mean difference (MD) and its 95% CI for continuous outcomes. Subgroup analysis was planned to explore potential sources of variability in observed treatment effect where possible (paediatric versus adult population, diabetic versus non diabetic, trial quality items, timing of peritonitis or other outcome). Heterogeneity of treatment effects between studies was formally tested using the Q (heterogeneity χ^2) and the I^2 statistics. When appropriate, summary estimators of treatment effects were calculated using a random effects model with RR and its 95% CI. Where data on the number of subjects with events (e.g. number of subjects with one or more episodes of peritonitis) were available, the RR was calculated as the ratio of the incidence of the event (one or more episodes) in the experimental treatment group over the incidence in the control group. Where data on the number of episodes were available, then the RR was calculated as the ratio of the rate of the outcome (e.g. the peritonitis rate) in the experimental treatment group (given by number of episodes of the outcome over total patient months on PD) over the rate in the control group. It was also planned that if sufficient RCTs were identified, an attempt would be made to assess for publication bias using a funnel plot (Egger 1997).

RESULTS

Description of studies

We identified twelve RCTs comparing double bag, Y-set and standard transfer systems with a total of 991 randomised patients (Cheng 1994; Churchill 1989; Dryden 1992; Harris 1996; Kiernan 1995; Li 1996; Li 1999; Lindholm 1988; Maiorca 1983; Monteon 1998; Owen 1992; Rottembourg 1987). One study (Monteon 1998) compared all three system types, seven compared only Y-set with standard systems (Cheng 1994; Churchill 1989; Li 1996; Lindholm 1988; Maiorca 1983; Owen 1992; Rottembourg 1987), one compared only double bag with standard systems (Dryden 1992) and three compared only double bag with Y-set systems (Harris 1996; Kiernan 1995; Li 1999). Some of the trials' reports did not include data relevant to all this review's outcomes or reported these data

in a manner that precluded inclusion in the meta-analyses (e.g. standard deviations were not available). Of all authors which were contacted for clarification and requests of additional information, only one replied (Harris 1996). As a consequence, some of the meta-analyses include fewer studies and fewer patients than might be expected. The publication of the studies were fairly evenly spread over a 16 year period from 1983 (Maiorca 1983) to 1999 (Li 1999).

A search performed in January 2005 identified three potential studies which were not relevant to this review (Huang 2001; Li 2002; Ong 2003). In this 2013 updated review, we excluded six new trials (Bailie 1990; Burkart 1990; de Fijter 1994; Lee 1997; Tan 2005; Wong 2006); one is awaiting classification (Correa-Rotter 1997a).

Risk of bias in included studies

Details of the methodological quality of the included RCTs are outlined in the description of included studies. Only four studies described the method of randomisation. One described a probably secure method of random allocation (Monteon 1998, central list of random numbers with order of allocation sent to participating centres in sealed envelopes). Two did not completely describe their method of random allocation (Churchill 1989, "variable blocking factor, by the coordinating centre", no other details given; Maiorca 1983, "closed envelope system", no other details given). Cheng 1994 described an unclear method of random allocation (random number tables but "investigators were not blind to what treatment previously recruited patients received", i.e. the next treatment could be anticipated). All twelve had parallel designs. Only two (Cheng 1994; Lindholm 1988) failed to describe withdrawals and dropouts. None of the study reports clearly stated that data were analysed on an intention to treat basis, although for only four (Harris 1996; Li 1999; Maiorca 1983; Monteon 1998) was it clear that analysis was not on an intention-to-treat basis. Blinding or masking was infrequently described and none of the studies stated specifically that patients, healthcare providers or outcome assessors were masked/blinded to the intervention.

Effects of interventions

Y-set versus standard spike systems

The use of the Y-set compared to standard spike systems was associated with a significantly lower risk of peritonitis (Analysis 1.1 (7 trials, 485 patients): RR 0.64, 95% CI 0.53 to 0.77), peritonitis rate (Analysis 1.2 (8 trials, 7417 patient-months): RR 0.49, 95% CI 0.40 to 0.61) but no difference in exit-site/tunnel infection (Analysis 1.3 (3 trials, 226 patients): RR 1.02, 95% CI 0.72 to 1.46) and rate (Analysis 1.4 (2 trials, 2841 patient-months): RR 1.24, 95% CI 0.91 to 1.69).

A number of different definitions of "technique failure" (Analysis 1.5, Analysis 1.6) reported in the studies were considered in this review including: (i) switch to haemodialysis, (ii) switch to different transfer set and (iii) no longer on allocated treatment for whatever reason. Overall, there was no significant difference in the risk of technique failure with the Y-set compared to standard spike systems with any of these definitions. There was also no difference in the risk of catheter removal (Analysis 1.7 (1 trial, 40 patients): RR 0.33, 95% CI 0.04 to 2.94). Only a single study which compared Y-set with standard systems reported data on all-cause (Analysis 1.8 (1 study, 69 patients): RR 1.12, 95% CI 0.81 to 1.56) and peritonitis-related (Analysis 1.9 (1 study, 69 patients): RR 0.61, 95% CI 0.26 to 1.44) hospitalisation, and showed no significant difference in the risk. There was also no significant difference in the risk of all-cause mortality with the Y-set compared to standard spike systems (Analysis 1.10 (5 trials, 355 patients): RR 1.03, 95% CI 0.48 to 2.21). Heterogeneity was not significant in any of these analyses.

Double bag versus standard systems

There was no statistically significant difference with double bag systems compared to standard systems for the risk of peritonitis (Analysis 2.1 (2 trials, 170 patients): RR 0.43, 95% CI 0.29 to 0.62), the peritonitis rate (Analysis 2.2 (2 trials, 2110 patient-months): RR 0.31, 95% CI 0.20 to 0.47), technique failure (Analysis 2.3 (1 trial, 80 patients): RR 1.00, 95% CI 0.06 to 15.44), exit-site/tunnel infection (Analysis 2.4 (1 trial, 80 patients): RR 0.75, 95% CI 0.18 to 3.14) and all-cause mortality (Analysis 2.5 (1 trial, 80 patients): RR 1.00, 95% CI 0.21 to 4.66) with no significant heterogeneity in any analysis.

Y-set or double bag systems versus standard systems

The combined analysis of Y-set or double bag systems compared to standard systems demonstrated a significant reduction in the risk of peritonitis (Analysis 3.1 (8 trials, 626 patients): RR 0.58, 95% CI 0.49 to 0.68) and peritonitis rate (Analysis 3.2 (11 trials, 10082 patient-months): RR 0.55, 95% CI 0.42 to 0.32) but no significant difference in the risk of exit-site/tunnel infection (Analysis 2.3 (3 trials, 264 patients): RR 1.00, 95% CI 0.71 to 1.42) and rate (Analysis 3.4 (2 trials, 2841 patient-months): RR 1.24, 95% CI 0.91 to 1.69), catheter removal (Analysis 3.5 (1 trial, 40 patients): RR 0.33, 95% CI 0.04 to 2.94), technique failure by various definitions (Analysis 3.6 and Analysis 3.7), the number of patients hospitalised due to any cause (Analysis 3.8 (1 trial, 69 patients): RR 1.12, 95% CI 0.81 to 1.56) or number of patients hospitalised due to peritonitis (Analysis 3.9 (1 trial, 69 patients): RR 0.61, 95% CI 0.26 to 1.44) and all-cause mortality (Analysis 3.10 (6 trials, 435 patients): RR 1.03, 95% CI 0.52 to 2.03). There was significant heterogeneity in the analysis of peritonitis rate (heterogeneity $\chi^2 = 26.78$, $P = 0.003$, $I^2 = 62.7\%$) caused mainly by the trial of Kiernan 1995 which had a shorter follow-up duration compared to all others.

Double bag systems versus Y-set systems

There was no significant difference with double bag compared to Y-set for the risk of peritonitis (Analysis 4.1 (3 trials, 292 patients): RR 0.59, 95% CI 0.35 to 1.01), peritonitis rate (Analysis 4.2 (4 trials, 4319 patients-months): RR 0.90, 95% CI 0.49 to 1.66), exit-site/tunnel infection rate (Analysis 4.3 (2 trials, 2319 patient-months): RR 1.04, 95% CI 0.52 to 2.06), technique failure by various definitions (Analysis 4.4, Analysis 4.5). There was also no difference in catheter removal/replacement (Analysis 4.6 (1 trial 63 patients): RR 0.10, 95% CI 0.01 to 1.81) and all-cause mortality (Analysis 4.7 (2 trials, 193 patients): RR 0.98 95% CI 0.25 to 3.43). The analysis of peritonitis rate showed significant heterogeneity (heterogeneity $\chi^2 = 12.24$, $P = 0.007$, $I^2 = 75.5\%$) which is imputable to the trial of Kiernan 1995. This trial had a shorter follow-up duration compared to all others.

Quality of Life

Only two studies reported quality of life data (Harris 1996; Li 1999). Both compared a double bag with a Y-set system. Harris 1996, using a Lickert scale, reported significantly greater "ease of use" and Li 1996, using a 6-item questionnaire, reported significantly greater "patient acceptability" with the double bag system. It was unclear how well-validated these instruments of assessment are in this particular setting.

DISCUSSION

This systematic review of double bag or Y-set versus standard transfer systems for CAPD has demonstrated that disconnect (double bag and Y-connection) systems are superior to conventional spike (or luer lock) connect systems for the prevention of peritonitis. There was no statistically significant advantage of twin bag systems compared with Y-systems, although the former were associated with a trend towards fewer affected patients with peritonitis (P = 0.05).

To our knowledge, the present study represents the most comprehensive systematic review of the relative benefits and harms of double bag or Y-set systems in PD patients. Two additional reviews have now been published and relate to the use of anti-microbial strategies (Strippoli 2004a) and other catheter-related interventions including catheter type and surgical techniques for insertion of the PD catheter (Strippoli 2004b) used to prevent PD peritonitis.

The most likely reason for the observation that disconnect systems are superior to conventional spike systems is a reduction of inadvertent peritoneal microbial contamination during connections with Y-set and twin bag systems as a result of the "flush before fill" manoeuvre (Bazzato 1980). Although the elimination of one connection procedure by twin bag systems should theoretically further reduce peritonitis episodes beyond that achieved by Y-connection systems, this was unable to be demonstrated in our study. In contrast in a previous version of this review (Daly 2000) we reported a significantly lower risk of experiencing peritonitis episodes with double bag systems compared with Y-systems (odds ratio 0.44, 95% CI 0.27 to 0.71). This apparent disparity may be partly explained by the more conservative statistical approach adopted in the present analysis (random effects model) compared with the previous (fixed effects model). In order to better assess the robustness of our statistical findings, we also additionally evaluated peritonitis rates as episodes/month (rather than just number of patients experiencing peritonitis) and again demonstrated no statistically significant differences between the two disconnect systems. Similar findings were observed for the other outcome measures evaluated, including exit-site/tunnel infections, catheter removal, technique survival and all-cause mortality.

These results support the recommendations of the British Renal Association (BRA) and the Caring for Australians with Renal Impairment (CARI) guidelines against the use of conventional spike connection systems. Although the International Society of Peritoneal Dialysis and K/DOQI clinical practice guidelines make no specific recommendations about connection methodology, spike and luer lock connect system usage has generally been declining in recent years. In the United Kingdom, the use of connect PD systems has decreased from 22% in 1998 to less than 1% in 2002 (Ansell 1998). A similar experience has been reported in Australia and New Zealand (Johnson 2003).

The strength of this investigation is that it represents a comprehensive systematic review based on a previous publication of a detailed protocol, rigid inclusion criteria for RCTs only, and a comprehensive multi-database literature search. Data extraction, data analysis and method quality assessment were performed by two independent investigators, and consistency was checked with an additional reviewer. Furthermore, infectious outcomes were separately examined in terms of rates per patient-month (Table 1; Table 2) and the number of patients affected in order to maximise statistical power and to verify the robustness of statistical analyses.

The main weakness of this study was the relative paucity of quality RCTs identified. The vast majority of studies evaluated failed to specify whether randomisation allocation was concealed, outcome assessors were blinded or data were analysed on an intention to treat basis. Many studies were small and often short in duration, so that the possibility of a type 2 statistical error for some of the less frequently observed outcome measures (e.g. catheter loss) could not be excluded. Moreover, evidence of trial heterogeneity was found in some analyses of peritonitis rates (twin bag versus Y-set), which most likely reflected significant inter-trial variation in durations of follow-up. These issues reduce the strength of the conclusions that have been drawn in this review.

AUTHORS' CONCLUSIONS

Implications for practice

Disconnect (twin bag and Y-set) systems are superior to conventional spike systems with respect to the prevention of peritonitis. No clear advantage of twin bag over Y-set systems could be shown, although available trials were limited.

Implications for research

Peritonitis is the most frequent serious complication of CAPD. It is essential that innovations in CAPD technique or technology designed to reduce peritonitis rates are subject to rigorous assessment by well-designed RCTs. This review demonstrates that the above interventions have been very poorly studied to date. There is an obvious need in this area for well-designed, RCTs (with clear descriptions of trial methodologies). The double bag and Y-set systems should be the standard against which future design modifications in CAPD transfer technology are compared. If more than one intervention is being considered clinical trials should be designed to identify clearly to which intervention beneficial or adverse effects can be attributed. There is likely to be no additional research benefit in further trials comparing double bag, Y-set and standard CAPD exchange systems.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Cheng 1994

Methods	RCT Method of random allocation: not described. However, states "since the investigators were not blind to the treatment previously recruited patients received, there might be a tendency to recruit older, less educated and diabetic patients with poorer eyesight and manual dexterity when treatment with UXVD was anticipated and to recruit younger and more educated patients when treatment with the O-set was anticipated." Masking: not mentioned. Description of withdrawals/dropouts: not mentioned. Analysis on intention to treat basis: unclear. Duration of follow-up: treatment group - 802 patient-months; control group - 838 patient-months.
Participants	All 100 patients starting CAPD over two years in a tertiary referral and satellite centre. 38 in treatment and 31 in control groups (also 31 in UVXD group).

Cheng 1994 *(Continued)*

	Exclusion criteria: age <10 or >70 years, living related transplant anticipated within 6 months of treatment. Unable to afford Y-set. Male:female ratio: treatment group - 20:18; control group - 17:14. Age (mean, range): treatment group - 34.9 (21-59) years; control group - 46.1 (23-65) years. Primary renal disease: treatment group - glomerulonephritis (11), pyelonephritis (3), diabetes mellitus (3), SLE/vasculitis/myeloma (1), unknown (13). Co-morbidity: treatment group - diabetes (1); control group (3).
Interventions	Y-set (O-set)(treatment) vs conventional spike (control) vs UVXD (excluded from this review). Sodium hypochlorite disinfectant (Amuchina) was retained in O-set connections between exchanges.
Outcomes	Peritonitis Exit site infections Hospitalisation Costs
Notes	A third group used UVXD - data from this group not included in this review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	C - Inadequate

Churchill 1989

Methods	RCT Method of random allocation - at co-ordinating centre "using variable blocking factor". Masking: not mentioned. Withdrawals/dropouts: numbers and reasons clearly stated; treatment group - 14 (transplant - 5; haemodialyses - 4; intermittent peritoneal dialysis - 1; recovery of renal function - 1; discontinued dialysis - 3); control group - 16 (transplant - 3; haemodialysis - 6; intermittent peritoneal dialysis - 3; recovery of renal function - 1; discontinued dialysis - 3). Analysis on intention to treat basis: unclear. Duration of follow-up: treatment group - 452 patient-months; control group - 467 patient-months.
Participants	124 new CAPD patients. 61 were in treatment group and 63 in control group. Exclusion criteria: age <18, likely to die in 6 months, previous complications on CAPD. Male:female ratio: not given. age - not given.
Interventions	Y-connector (plus Amuchina)(treatment) vs standard spike (Baxter II and III)(control).

Churchill 1989 *(Continued)*

Outcomes	Peritonitis Exit site infections Technique survival (Kaplan- Meier).
Notes	Hypochlorite disinfectant in Y-set.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Dryden 1992

Methods	RCT Method of random allocation: not described. Masking: not mentioned Description of withdrawals and dropouts: numbers and reasons clearly stated; treatment group - 12 (died - 3; transplant - 5; haemodialysis - 1; recurrent infection - 1; catheter failure -1; recovery of renal function - 1); control group - 12 (died - 3; transplant - 5; haemodialysis - 1; recurrent infections - 2; catheter failure - 1). Analysis on intention to treat basis: unclear. Duration of follow-up (mean, range):14.1 (3 - 36) months. treatment group - 564 - patient-months; control group - 564 patient-months.
Participants	80 CAPD patients (new and established) at a single centre 40 in treatment and 40 in control groups. Male:female ratio: treatment group - 23:17; control group - 26:14. Age (mean, range): 49 (20 - 67) years. Co-morbidity: treatment group - diabetes (5); control group (7).
Interventions	Y-set (Freeline Solo) using drain/flush/fill (treatment) vs standard (Baxter II)(control).
Outcomes	Peritonitis Exit site infections
Notes	Hypochlorite not used in this system. Povidone iodine cap protectors used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Harris 1996

Methods	RCT Method of random allocation: not described but states "patients stratified into three groups". Masking: not mentioned Description of withdrawals and dropouts: numbers and reasons clearly stated. Overall - 10 (died - 2; transplant - 3; recovery of renal function - 1; blindness - 1; transfer to other unit - 1; haemodialysis - 2). It also stated " no differences in reasons for early termination between patients on the basic Y or Freeline Solo systems". Analysis on intention to treat basis: data from Group 3 were not analysed because of its high dropout rate but data from the other two groups "were analysed on an intention to treat basis". Duration of follow-up (mean, SD): treatment group: group 1 - 9.1(3.9) months; group 2 - 9.9(3.5) months; control group: group 1 8.5(3.2) months; group 2 - 11.5(3.6) months treatment group - 328 patient-months; control group - 303 patient-months.
Participants	New and established CAPD patients - group 1 - new patients (39); group 2 - established patients with no peritonitis or exit site infections in previous 12 months or with new catheter (24); group 3 - established patients with 1-3 catheter-related infections in previous 12 months (9). Because of high dropout rate data from group 3 were not reported nor analysed. Overall: 33 in treatment group and 30 in control group. Inclusion criteria: ≥ 18 years old; ability to perform exchanges without nursing assistance; informed consent. Exclusion criteria: within 2 months of catheter-related infection; more than 3 separate catheter-related infections in previous year unless catheter subsequently replaced. Male:female ratio: treatment group - 13:20; control group - 11:19. Age (mean, SD): treatment group - group 1 - 55(17) years; group 2 - 59(11) years; control group - group 1 - 51(17) years; group 2 - 60(15) years. Co-morbidity: treatment group - diabetes (9); control group - diabetes (6).
Interventions	Double bag (Baxter Freeline Solo)(treatment) vs Basic Y (control). All had double-cuffed silastic Tenckhoff catheters. Catheters immobilised.
Outcomes	Peritonitis Exit site infections Cost Training time Hospitalisation Catheter removal "Ease of use" scale
Notes	Data from group 3 not reported nor analysed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Kiernan 1995

Methods	RCT Method of random allocation: not described but states "stratified for race and than randomly assigned". Masking: patients and healthcare workers not masked. Description of withdrawals and dropouts: numbers and reasons clearly stated; treatment group - 4 (transplant - 1; CAPD drainage problems - 2; recovery of renal function - 1); control group - 15 (haemodialysis - 5; transplant - 3; transfer to other unit - 1; CCPD - 1; died - 1). Analysis on intention to treat basis: unclear. Duration of follow-up (mean, SD): treatment group - 4.1(2.6) months; control group - 4.3(2.5) months.
Participants	35 new and 47 established CAPD patients in single unit. 41 in treatment and 41 in control groups. Male:female ratio: Age (mean,SD): treatment group - 54.1(15.2) years; control group - 55.2(14.5) years. Co-morbidity: treatment group - diabetes (15); HIV positive (4); cardiovascular disease (20); control group - diabetes (10); HIV positive (4); cardiovascular disease (13).
Interventions	UltraTwin bag system (Baxter) (luer lock between Tenckhoff and double bag, no spiking required, flush/drain/fill)(treatment) vs Ultra Y-set system (Baxter) (luer lock between catheter and Y-set, new dialysate bag spiked, flush/drain/fill)(control).
Outcomes	Peritonitis
Notes	Treatment group - whites (19); African-americans (22); control group - whites (18); African-americans (23). Study terminated at interim analysis (300 patient-months) because of statistically significant difference in infection rates between groups.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Li 1996

Methods	RCT Method of random allocation: not described. Masking: states single-blinded but unclear who is blinded patients, healthcare providers or healthcare assessors. Description of withdrawals and dropouts: numbers and reasons clearly stated; total - 4 (died - 3; transplant - 1) Analysis on intention to treat basis: unclear

Li 1996 *(Continued)*

	Duration of follow-up: 12 months
Participants	40 new ESRD patients in single unit. 20 in treatment group and 20 in control group. Male:female ratio: treatment group - 9:11; control group - 6:14. Age (mean,SD): treatment group - 50(8) years; control group 47(15) years. Co-morbidity: treatment group - diabetes (5); HBsAg carriers (2); control group - diabetes (4); HBsAg carriers (3).
Interventions	Y-set (Ultraset, Baxter) with drain/flush/fill (treatment) vs conventional spike (control). 3 exchanges per day.
Outcomes	Peritonitis Exit site infections Hospitalisation Duration of training Mortality
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Li 1999

Methods	RCT Method of random allocation: not described; states randomisation was single-blinded but remains unclear who was blinded. Masking: states single- blinded study but unclear who was blinded. Description of withdrawals and dropouts: numbers and reasons clearly stated - treatment group - 9 (opted not to use Y-set - 7; incomplete data - 2). Analysis on intention to treat basis: no Duration of follow-up: all patients followed for at least 12 months. Treatment group - 937 patient-months; control group - 734 patient-months.
Participants	120 new ESRD patients admitted to CAPD programme. 60 in treatment group and 60 in control group (data on only 51 reported, see above). Male:female ratio: treatment group - 28:32; control group - 26:25. Age (mean,SD): treatment group - 53.4(13.4) years; control group 49.3(14.2) years. Primary renal disease: treatment group - glomerulonephritis (14); diabetes (11); adult polycystic kidney disease (2); hypertension (3); renal stone disease (5); others/unknown (25); control group -

Li 1999 *(Continued)*

	glomerulonephritis (13); diabetes (11); adult polycystic kidney disease (4); hypertension (3); renal stone disease (0); others/unknown (20). Co-morbidity: treatment group - diabetes (15); HBsAg carriers (10); control group - diabetes (14); HBsAg carriers (5).
Interventions	Double bag disconnect system (Ultrabag, Baxter) "pre-assembled and sterilised as single unit". (treatment) vs Y-set disconnect system (Ultraset, Baxter)(control). 3 exchanges per day.
Outcomes	Peritonitis Exit site infections Patient acceptance Hospitalisation Catheter removal Mortality
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Lindholm 1988

Methods	RCT Method of random allocation: not described. Masking: not mentioned. Description of withdrawals and dropouts: not mentioned. Analysis on intention to treat basis: unclear. Duration of follow-up: treatment group - 284 patient-months; control group 255 patient-months.
Participants	58 patients with ESRD. 35 in treatment group and 23 in control group. Co-morbidity: overall - diabetes (15).
Interventions	Y-set (5F "safe-lock" take-off system, Fresenius, flush/drain/fill)(treatment) vs conventional CAPD systems (control).
Outcomes	Peritonitis
Notes	Authors stated that "we had problems with this study. The number of patients was envisaged to be 140, 58 were enrolled."

Risk of bias

Bias	Authors' judgement	Support for judgement

Lindholm 1988 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	B - Unclear

Maiorca 1983

Methods	RCT Method of random allocation: "closed envelope system" but no other details reported. Masking: not mentioned. Description of withdrawals and dropouts: number and reasons clearly stated - treatment group - 6 (died - 2; withdrawn because additives to CAPD bags - 1; CAPD stopped because of loss of ultrafiltration - 1; patient request to withdraw from trial - 1; progressive mental deterioration - 1); control group (died - 1; withdrawn because additives to CAPD bags - 1; recurrent peritonitis and switched to Y-set - 4; CAPD stopped because of loss of ultrafiltration - 1; patient request to withdraw from trial - 1; withdrew because of recurrent exit site infections - 2). Analysis on intention to treat basis: no Duration of follow-up (mean,SD): treatment group - 11.3(5.6)(range 3-24) months; control group - 11.7(6.1)(range 3-24) months. treatment group - 363 patient-months; control group - 351 patient-months.
Participants	62 new CAPD patients . 32 in treatment and 30 in control groups. Exclusion criteria: diabetes Male:female ratio: treatment group - 17:15; control group - 19:11. Age (mean,SD): treatment group - 55.1(14.3)(range 12-75) years; control group 55.5(17.5)(range 14-80) years.
Interventions	Y-connector with disinfectant (sodium hypochlorite, Amuchina) (Travenol, Lessines)(flush/drain/fill) (treatment) vs Standard (Travenol spike) (control).
Outcomes	Peritonitis Mortality
Notes	Hypochlorite used. Kaplan-Meir analysis also reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Monteon 1998

Methods	RCT

Monteon 1998 *(Continued)*

	Method of random allocation: "done centrally by one of the researchers following the Moses-Oakford method as described by Meinert, with the use of a list of random numbers. The order of allocation was sent to each participant centre in sealed envelopes. A copy of the assignment list was kept in the coordinating centre. At least three audit visits were done to each centre by trained nurses to certify that the envelopes were used in the order provided and that their content remained unknown to the personnel of the centre until the initiation of the treatment." Uneven randomisation in proportion double bag:Y-set:standard system - 2:2:1. Masking: none Description of withdrawals and dropouts: number and reasons clearly stated - total - 59 (randomised but did not begin study - 7; transplant - 10; died - 23; technique failure - 8; others - 11) states "no significant difference in dropouts or deaths among the groups" Analysis on intention to treat basis: no Duration of follow-up: "time at risk per patient" - double bag - 10.6 months; Y-set 11.8 months; standard system - 11.6 months. Total follow-up: double bag - 645.1 patient-months; Y-set - 670.8 patient-months; standard system - 337.4 patient-months.
Participants	154 new ESRD patients 147/154 randomised patients began study: double bag - 61; Y-set - 57; standard system - 29. Exclusion criteria: previous abdominal surgery, abdominal hernias, diverticulosis, cancer, AIDS. Male:female ratio: double bag - 33:28; Y-set - 37:20; standard system - 15:14. Age (mean,SD): double bag - 43.6(21.9) years; Y-set - 43.2(21.3) years; standard system - 39.7(19.0) years. Co-morbidity: diabetes - double bag (20), Y-set (19), standard system (15). "High risk, low educational and socioeconomic levels with high prevalence of malnutrition."
Interventions	Double bag vs Y-set vs standard spike system.
Outcomes	Peritonitis Exit site infections Hospitalisation Catheter removal Cost
Notes	Kaplan-Meir analysis also reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Owen 1992

Methods	RCT Method of random allocation: not described. Masking: not mentioned.

Owen 1992 *(Continued)*

	Description of withdrawals and dropouts: numbers and reasons clearly stated - treatment group - 20 (died - 3; transplant - 11; haemodialysis - 3; intermittent peritoneal dialysis or other CAPD system - 3); control - 18 (died - 5; transplanted - 3; haemodialysis - 10; transferred to intermittent peritoneal dialysis or CAPD - 0). Analysis on intention to treat basis: unclear. Duration of follow-up (median, range): treatment group - 9 (1-33) months; control group - 14 (1-34) months. treatment group - 375 patient-months; control group - 430 patient-months.
Participants	60 patients commencing CAPD. 30 in treatment group and 30 in control group. Inclusion criteria: "patients who could tolerate 2L fluid exchanges". Exclusion criteria: "Significant physical disabilities or severe visual impairment". Male:female ratio: treatment group - 16:14; control group - 15:15. Age (median, range): treatment group - 54 (11-79) years; control group - 56 (16-75) years.
Interventions	Y-set modification (O-system "modification of the Y-system with the ends of the connector joined to each other to form a closed circuit between exchanges"; flush before fill, ends soaked in hypochlorite prior to exchange) vs standard system (luer lock, System II, Baxter)
Outcomes	Peritonitis. Exit site infection. Technique failure Training time
Notes	Povidone iodine caps used. Kaplan-Meir analysis also reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Rottembourg 1987

Methods	RCT Method of random allocation: not described. Masking: not mentioned. Description of withdrawals and dropouts: not mentioned. Analysis on intention to treat basis: unclear. Duration of follow-up: treatment group - 277 patient-months (range 2-24); control group - 344 patient-months (range, 2-24).
Participants	55 new CAPD patients

Rottembourg 1987 *(Continued)*	27 patients in treatment group and 28 patients in control group. Exclusion criteria: three new patients excluded because they were "returning to Africa". Male:female ratio: treatment group - 12:15; control group - 16:12. Age (mean,SD): treatment group - 48.6(13.2) years; control group - 54.6(14.6) years. Primary renal disease: treatment group - diabetes (9); glomerulonephritis (6), interstitial nephritis (8); others/unknown (3); nephroangiosclerosis (1); control group - diabetes (10); glomerulonephritis (11), interstitial nephritis (3); others/unknown (2); nephroangiosclerosis (2)
Interventions	Y-set systems (3 different systems used - Y-set disposable disconnect system, one time use, two connections only, no disinfectant used, flush/drain/fill (Travenol); O-set reusable system, no disinfectant, reused for one month (Travenol) and 5F safe-lock system, flush/drain/fill (Fresenius)) (treatment) vs standard systems (luer lock or Reverse system (Travenol) or safe-lock with spray of chlorhexidine (Fresenius) (control).
Outcomes	Peritonitis
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Amato 1999	Not RCT though reports data from two previously published RCTs
Bailie 1990	Compares O-set with UVXD germicidal system
Balteau 1991	Not RCT
Buoncristiani 1989	Not RCT
Burkart 1990	Compared standard spike with Ultraset
Cancarini 1995	RCT but patients randomised to "flushing" versus "flushing plus in line disinfectant" not to Y-set, double-bag or standard spike systems
Correa-Rotter 1997	Abstract only publication, no data available September 2016
de Fijter 1994	Compared Y-connector CAPD with CCPD
Durand 1995	Not RCT
Garcia-Lopez 1994	Not RCT
Hall 1989	Possible quasi-RCT but compares two non-disconnect systems

Study	Reason for exclusion
Holley 1994	Not RCT
Huang 2001	Not RCT
Junor 1989	Not RCT
Lee 1997	Not RCT
Lempert 1986	Not RCT
Ong 2003	Comparisons not relevant to this review. Study compared two Y-disconnect systems.
Orange 1987	Not RCT
Piraino 1993	Not RCT
Port 1992	Not RCT
Ryckelynck 1988	Probable RCT but patients randomised to "soaking" or not "soaking" connectors in povidone iodine
Smith 1997	Not RCT and specifically concerns automated peritoneal dialysis and not CAPD
Smith 1997a	Not RCT and specifically concerns automated peritoneal dialysis and not CAPD
Tan 2005	Compared ANDY.disc system to Ultrabag system
Tielens 1993	Not RCT
Viglino 1989	RCT but comparing Y-set and modification of Y-set (Y-set with two short branches) no comparison with standard spike or double-bag systems
Viglino 1993	RCT but comparing Y-set and modification of Y-set (T-set with disinfectant) no comparison with standard spike or double-bag systems
Wong 2006	Compared ANDY-Disc system with UltraBag system
Wust 1985	Not RCT

DATA AND ANALYSES

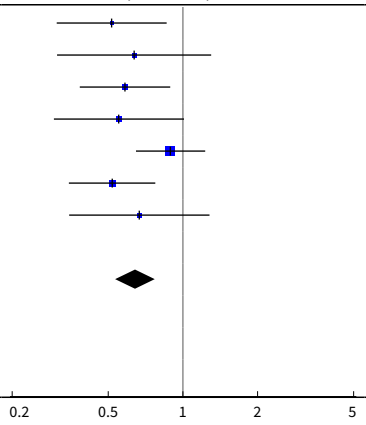
Comparison 1. Y-set systems versus standard systems

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with peritonitis	7	485	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.53, 0.77]
2 Peritonitis rate	8	7417	Risk Ratio (M-H, Random, 95% CI)	0.49 [0.40, 0.61]

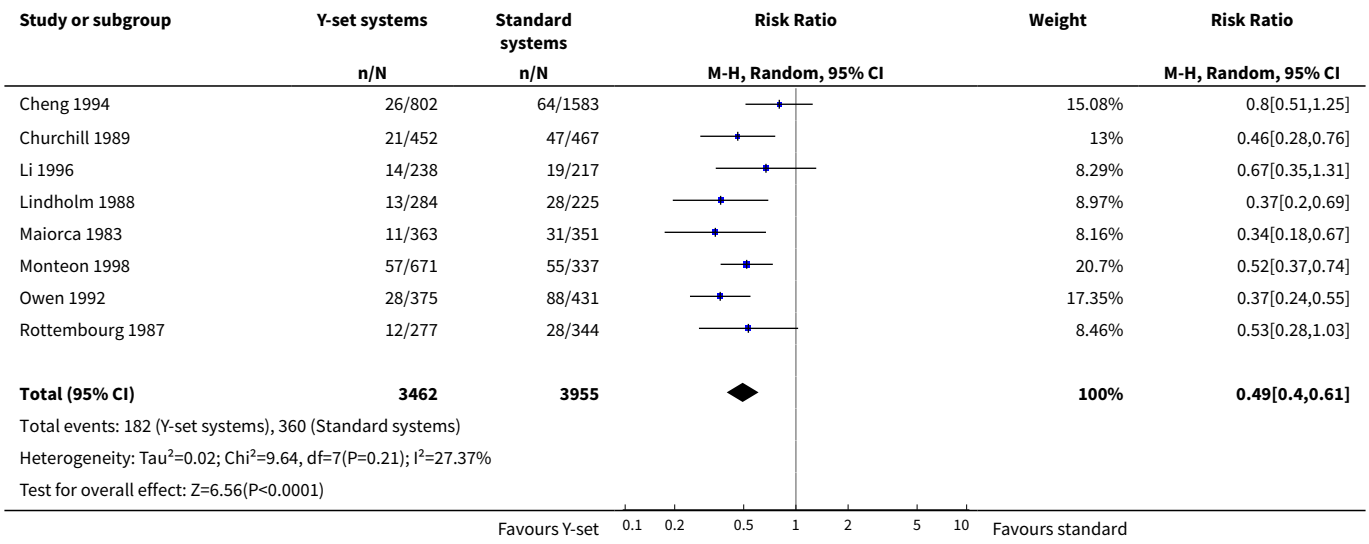
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Number of patients with exit site/tunnel infection	2	184	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.72, 1.46]
4 Exit-site/tunnel infection rate	2	2841	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.91, 1.69]
5 Number of patients switched to HD	2	184	Risk Ratio (M-H, Random, 95% CI)	0.45 [0.19, 1.05]
6 Number of patients no longer on allocated treatment for whatever reason	2	184	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.76, 1.46]
7 Number of patients who had CAPD catheter removed	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
8 Number of patients hospitalised (all cause)	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
9 Number of patients hospitalised (peritonitis)	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
10 All-cause mortality	5	355	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.48, 2.21]

Analysis 1.1. Comparison 1 Y-set systems versus standard systems, Outcome 1 Number of patients with peritonitis.

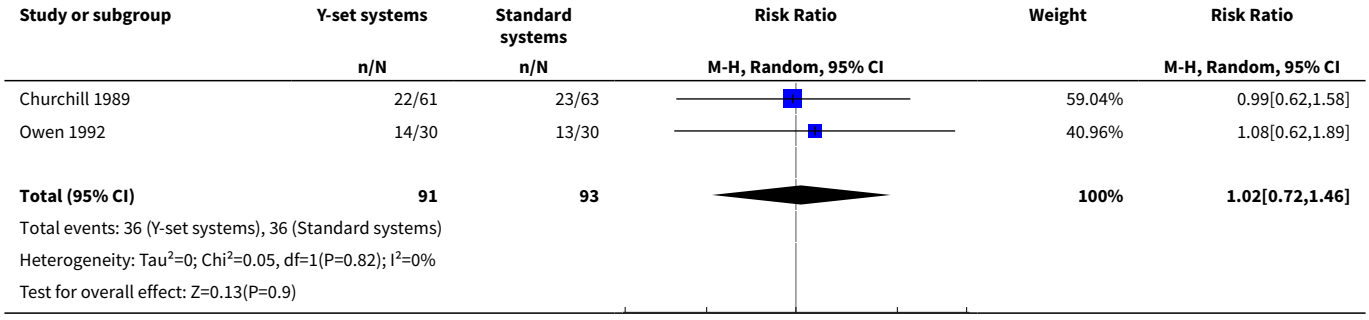
Study or subgroup	Y-set systems n/N	Standard systems n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Churchill 1989	15/61	30/63		12.18%	0.52[0.31,0.86]
Li 1996	7/20	11/20		6.36%	0.64[0.31,1.3]
Lindholm 1988	16/35	18/23		17.43%	0.58[0.38,0.89]
Maiorca 1983	10/32	17/30		8.91%	0.55[0.3,1.01]
Monteon 1998	35/57	20/29		28.41%	0.89[0.65,1.23]
Owen 1992	14/30	27/30		19.02%	0.52[0.35,0.77]
Rottembourg 1987	9/27	14/28		7.69%	0.67[0.35,1.28]
Total (95% CI)	**262**	**223**		**100%**	**0.64[0.53,0.77]**
Total events: 106 (Y-set systems), 137 (Standard systems)					
Heterogeneity: Tau^2=0; Chi^2=6.45, df=6(P=0.38); I^2=6.91%					
Test for overall effect: Z=4.75(P<0.0001)					



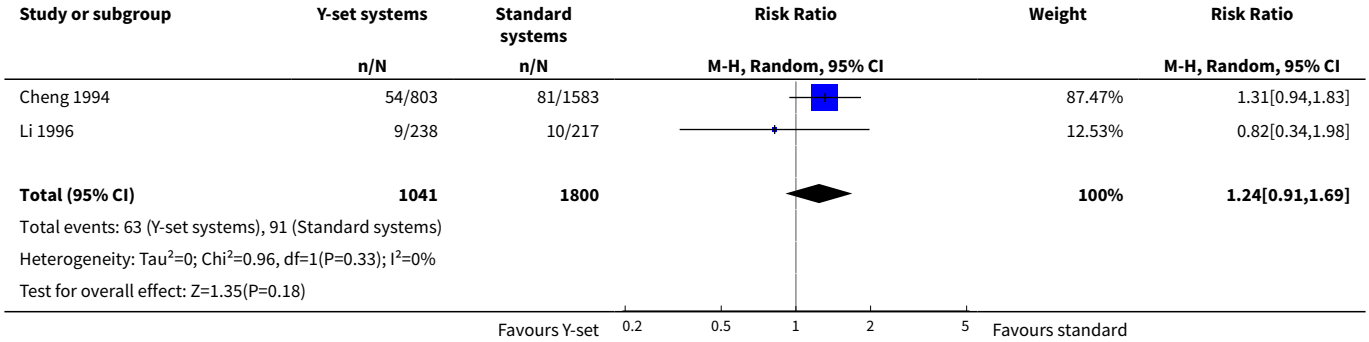
Analysis 1.2. Comparison 1 Y-set systems versus standard systems, Outcome 2 Peritonitis rate.



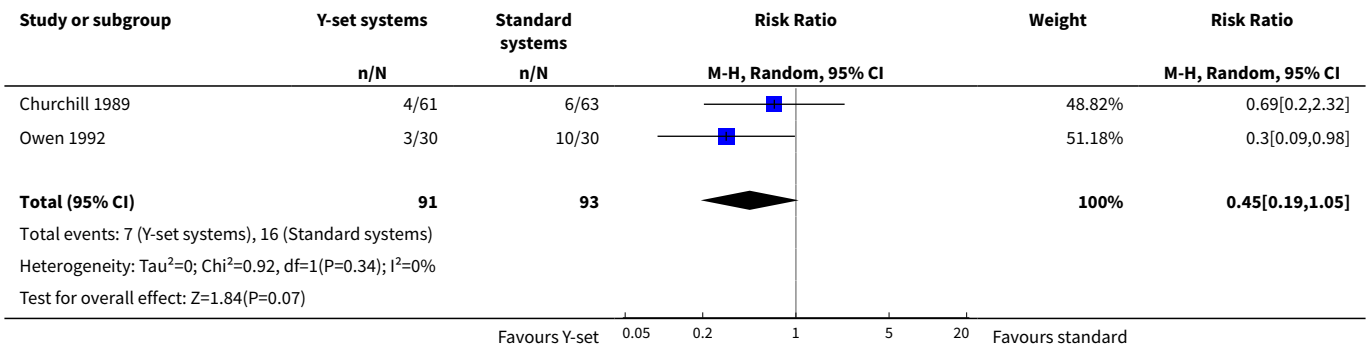
Analysis 1.3. Comparison 1 Y-set systems versus standard systems, Outcome 3 Number of patients with exit site/tunnel infection.



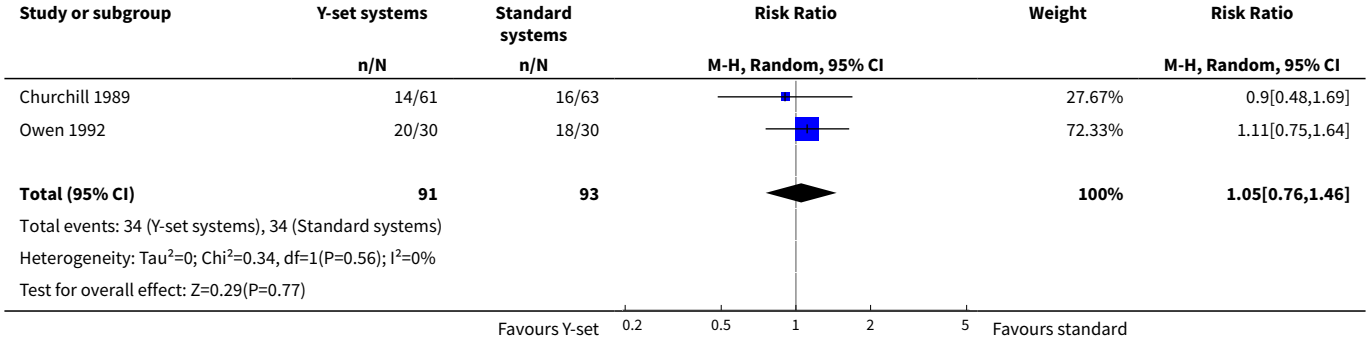
Analysis 1.4. Comparison 1 Y-set systems versus standard systems, Outcome 4 Exit-site/tunnel infection rate.



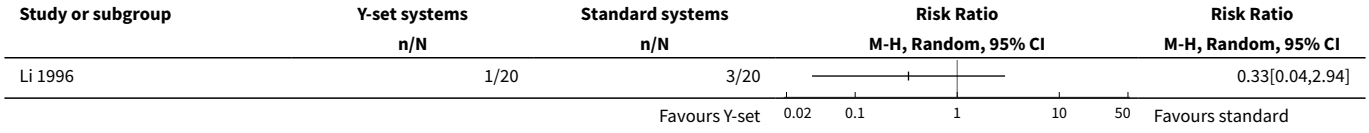
Analysis 1.5. Comparison 1 Y-set systems versus standard systems, Outcome 5 Number of patients switched to HD.



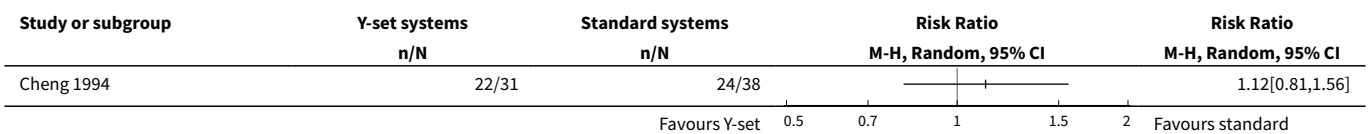
Analysis 1.6. Comparison 1 Y-set systems versus standard systems, Outcome 6 Number of patients no longer on allocated treatment for whatever reason.



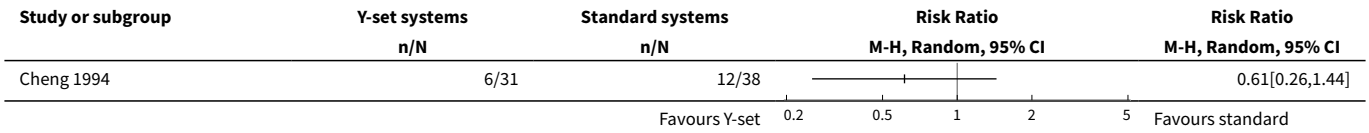
Analysis 1.7. Comparison 1 Y-set systems versus standard systems, Outcome 7 Number of patients who had CAPD catheter removed.



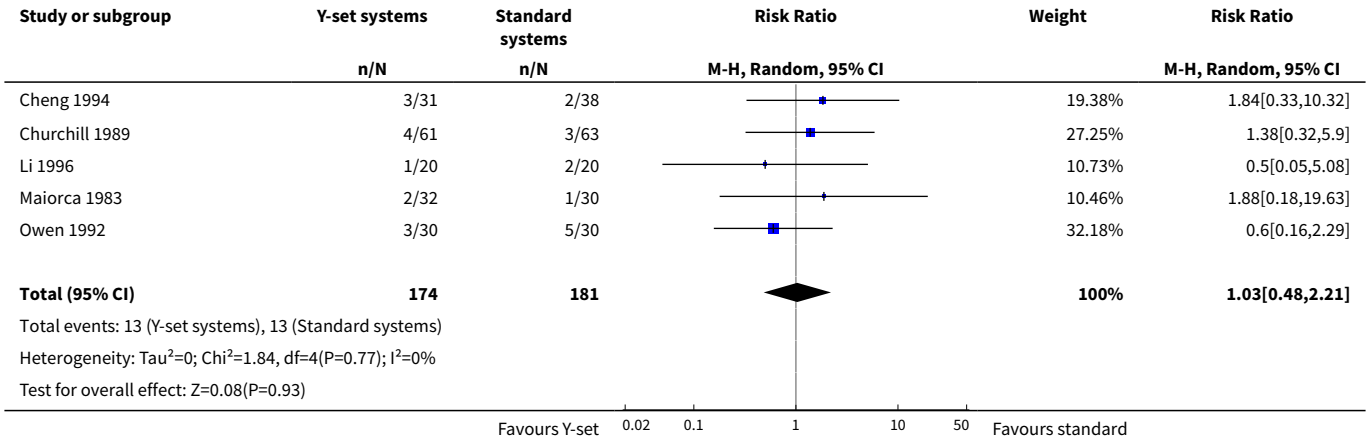
Analysis 1.8. Comparison 1 Y-set systems versus standard systems, Outcome 8 Number of patients hospitalised (all cause).



Analysis 1.9. Comparison 1 Y-set systems versus standard systems, Outcome 9 Number of patients hospitalised (peritonitis).



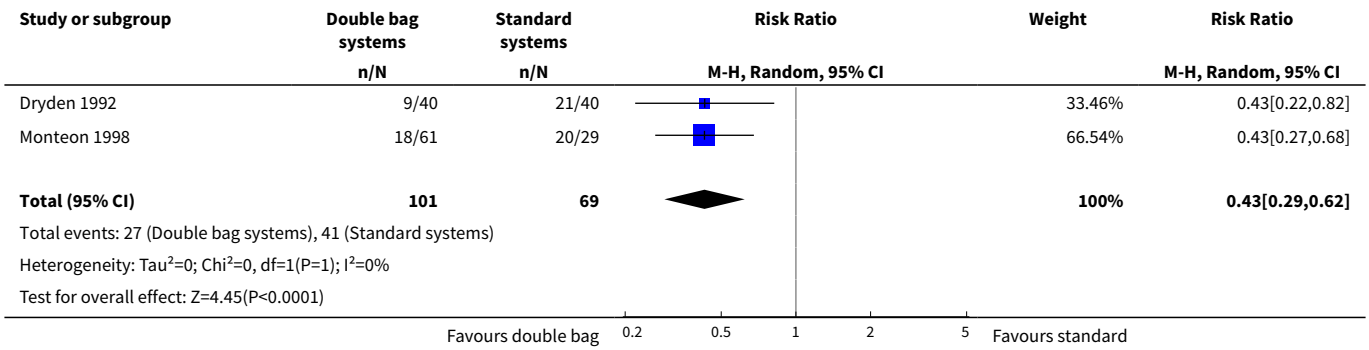
Analysis 1.10. Comparison 1 Y-set systems versus standard systems, Outcome 10 All-cause mortality.



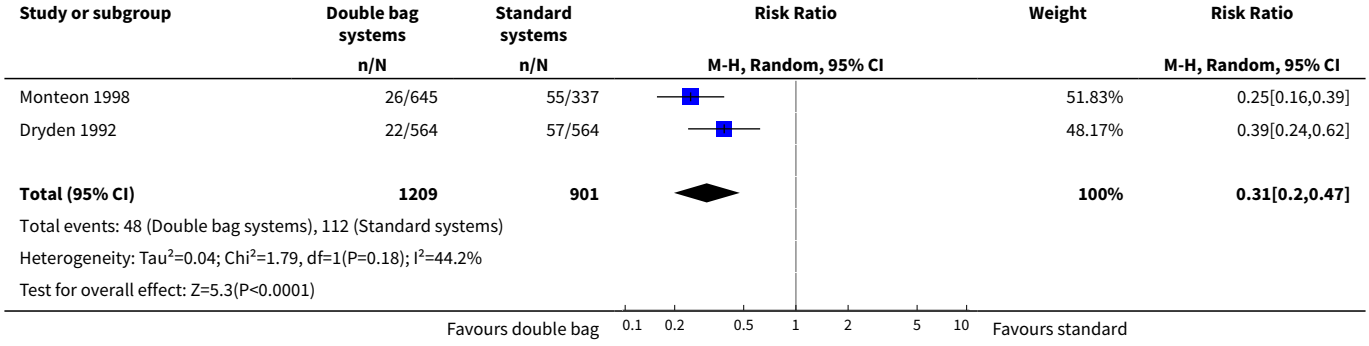
Comparison 2. Double bag systems versus standard systems

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with peritonitis	2	170	Risk Ratio (M-H, Random, 95% CI)	0.43 [0.29, 0.62]
2 Peritonitis rate	2	2110	Risk Ratio (M-H, Random, 95% CI)	0.31 [0.20, 0.47]
3 Number of patients switched to HD	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4 Number of patients with exit site infection	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
5 All-cause mortality	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

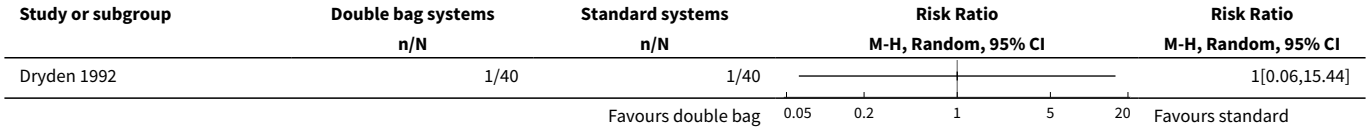
Analysis 2.1. Comparison 2 Double bag systems versus standard systems, Outcome 1 Number of patients with peritonitis.



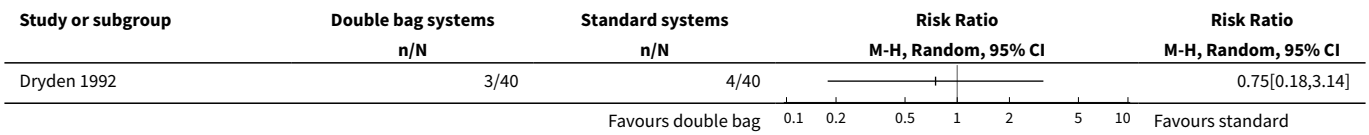
Analysis 2.2. Comparison 2 Double bag systems versus standard systems, Outcome 2 Peritonitis rate.



Analysis 2.3. Comparison 2 Double bag systems versus standard systems, Outcome 3 Number of patients switched to HD.

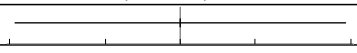


Analysis 2.4. Comparison 2 Double bag systems versus standard systems, Outcome 4 Number of patients with exit site infection.



Analysis 2.5. Comparison 2 Double bag systems versus standard systems, Outcome 5 All-cause mortality.

Study or subgroup	Double bag systems n/N	Standard systems n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Dryden 1992	3/40	3/40		1[0.21,4.66]

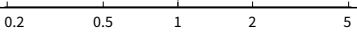


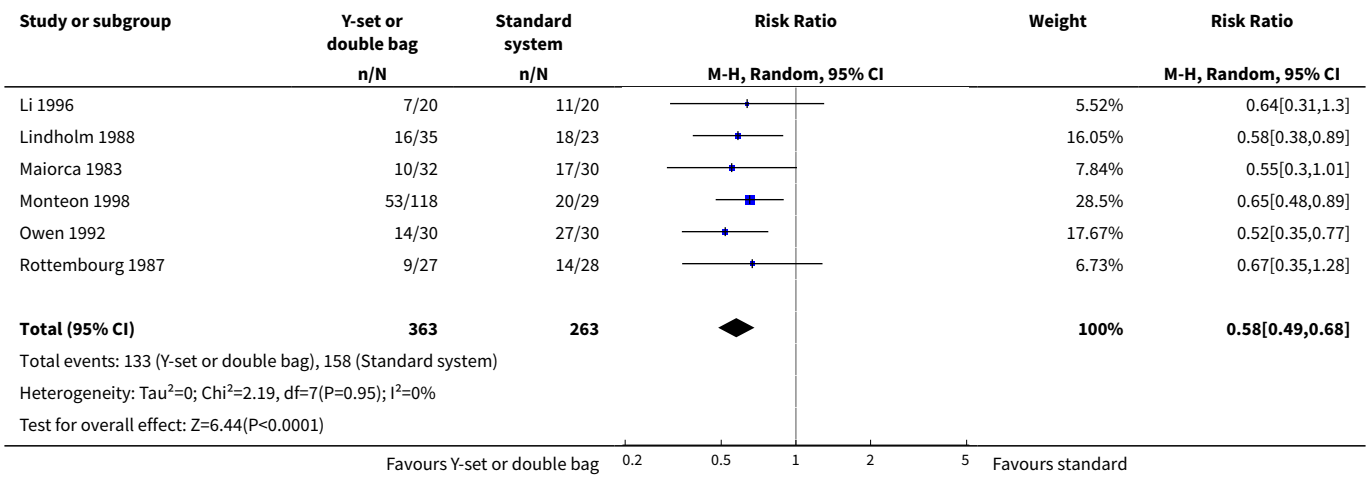
Comparison 3. Y-set or double bag systems versus standard systems

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with peritonitis	8	626	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.49, 0.68]
2 Peritonitis rate	11	10082	Risk Ratio (M-H, Random, 95% CI)	0.55 [0.42, 0.73]
3 Number of patients with exit-site/tunnel infection	3	264	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.71, 1.42]
4 Exit-site/tunnel infection rate	2	2841	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.91, 1.69]
5 Number of patients who had CAPD catheter removed	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
6 Number of patients no longer on allocated treatment for whatever reason	2	184	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.76, 1.46]
7 Number of patients switched to HD	3	264	Risk Ratio (M-H, Random, 95% CI)	0.48 [0.21, 1.09]
8 Number of patients hospitalised (all cause)	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
9 Number of patients hospitalised (peritonitis)	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
10 All-cause mortality	6	435	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.52, 2.03]

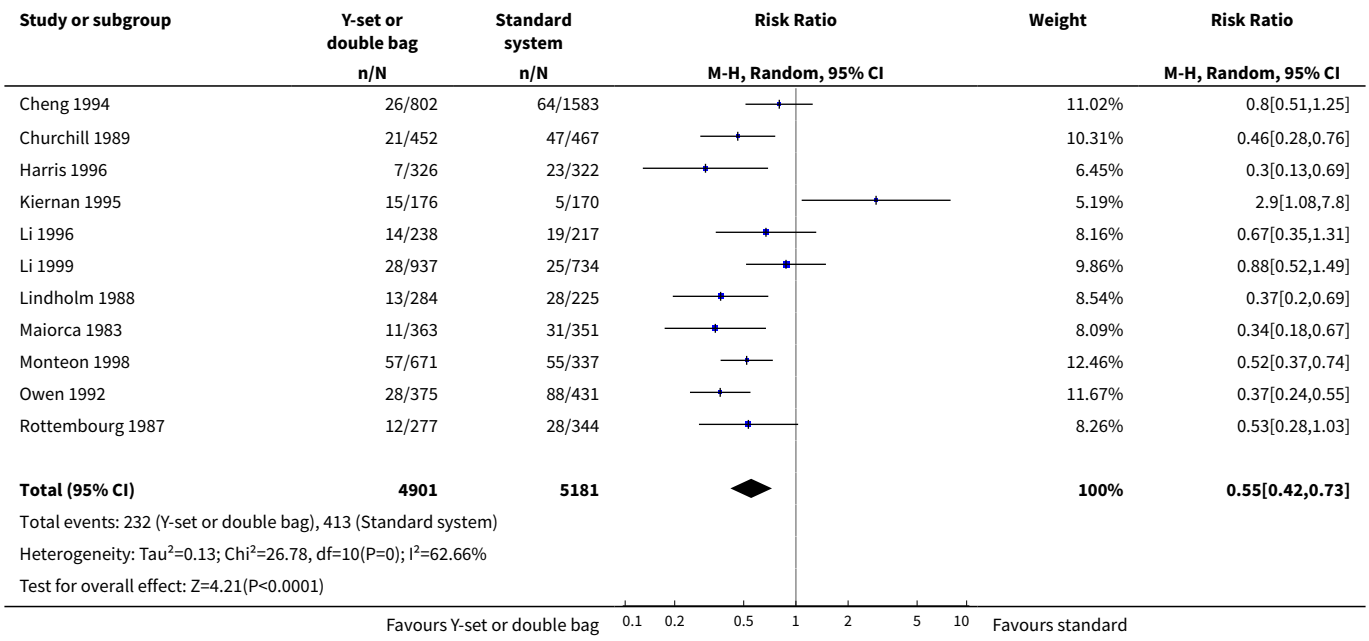
Analysis 3.1. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 1 Number of patients with peritonitis.

Study or subgroup	Y-set or double bag n/N	Standard system n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Churchill 1989	15/61	30/63		10.9%	0.52[0.31,0.86]
Dryden 1992	9/40	21/40		6.79%	0.43[0.22,0.82]

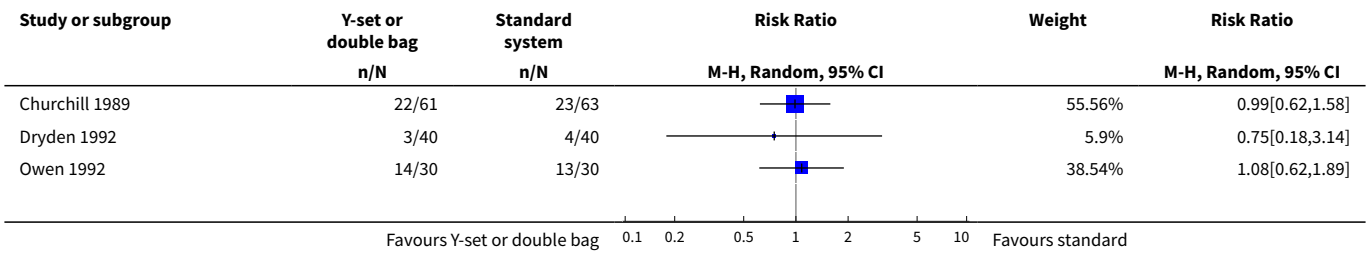


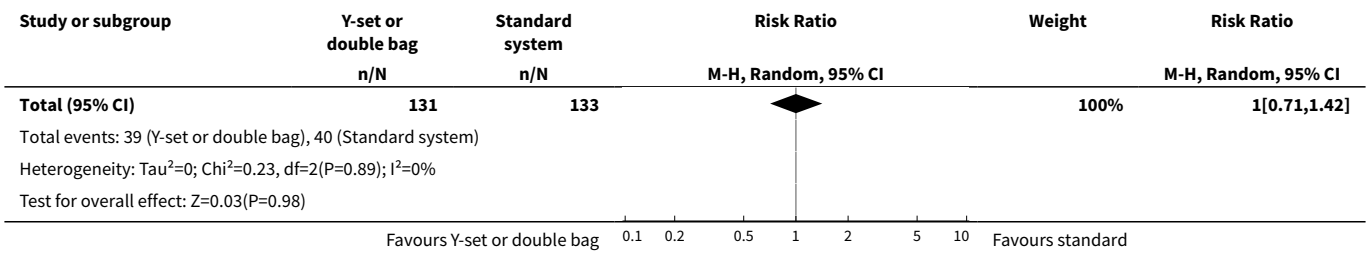


Analysis 3.2. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 2 Peritonitis rate.

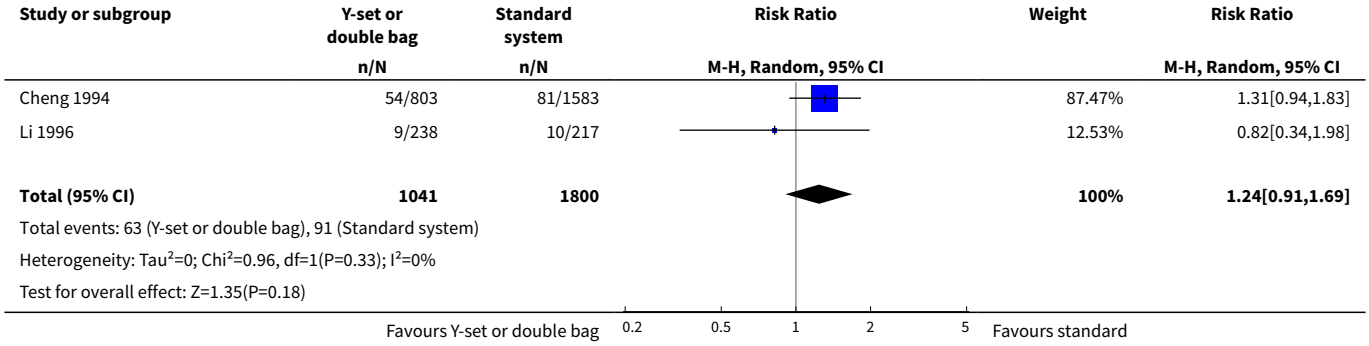


Analysis 3.3. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 3 Number of patients with exit-site/tunnel infection.

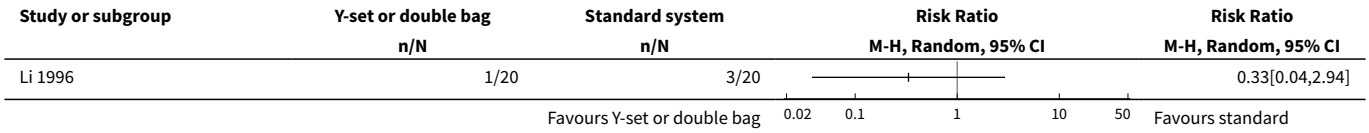




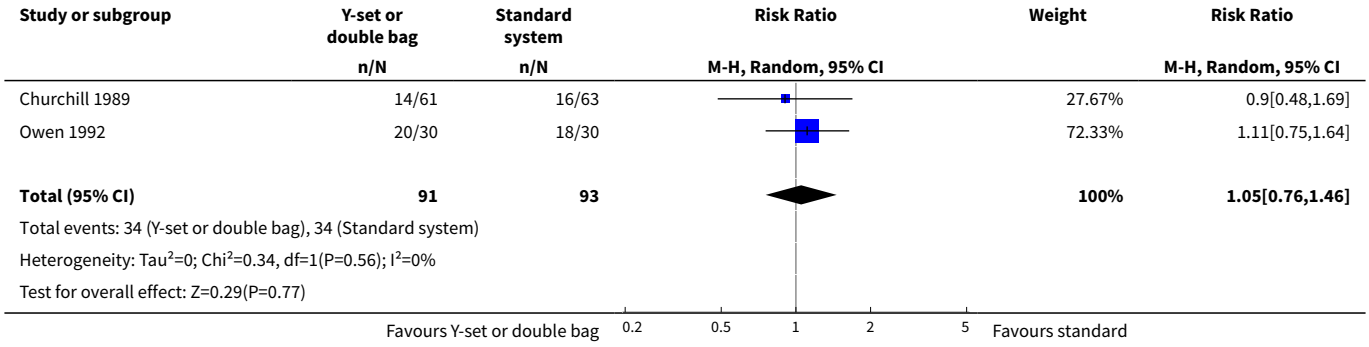
Analysis 3.4. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 4 Exit-site/tunnel infection rate.



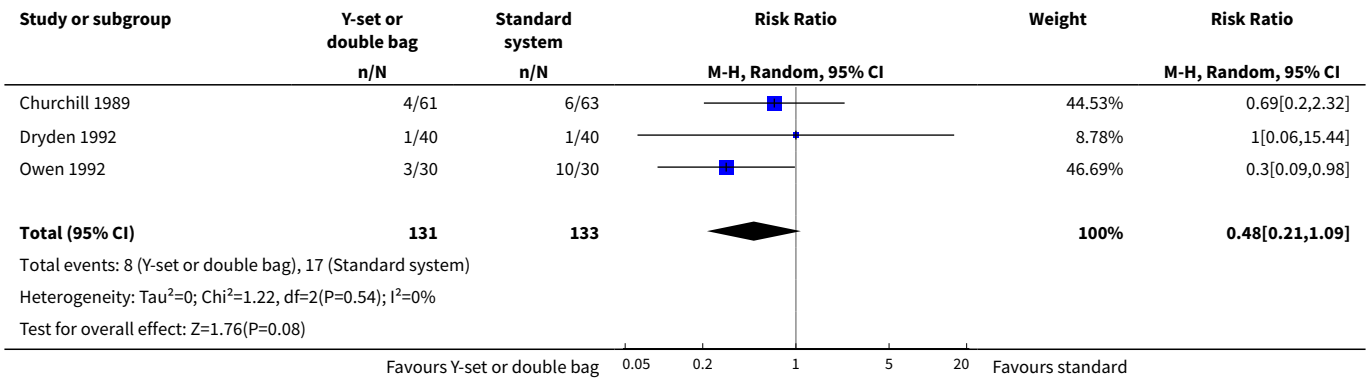
Analysis 3.5. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 5 Number of patients who had CAPD catheter removed.



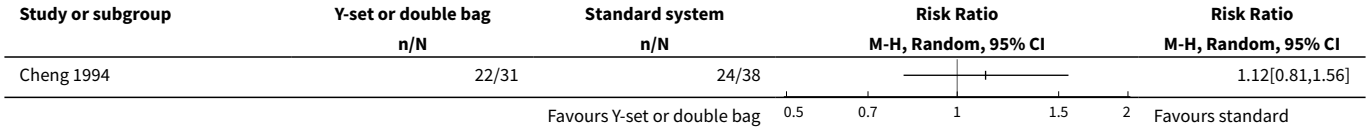
Analysis 3.6. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 6 Number of patients no longer on allocated treatment for whatever reason.



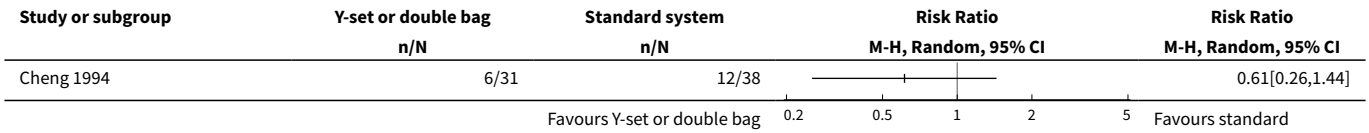
Analysis 3.7. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 7 Number of patients switched to HD.



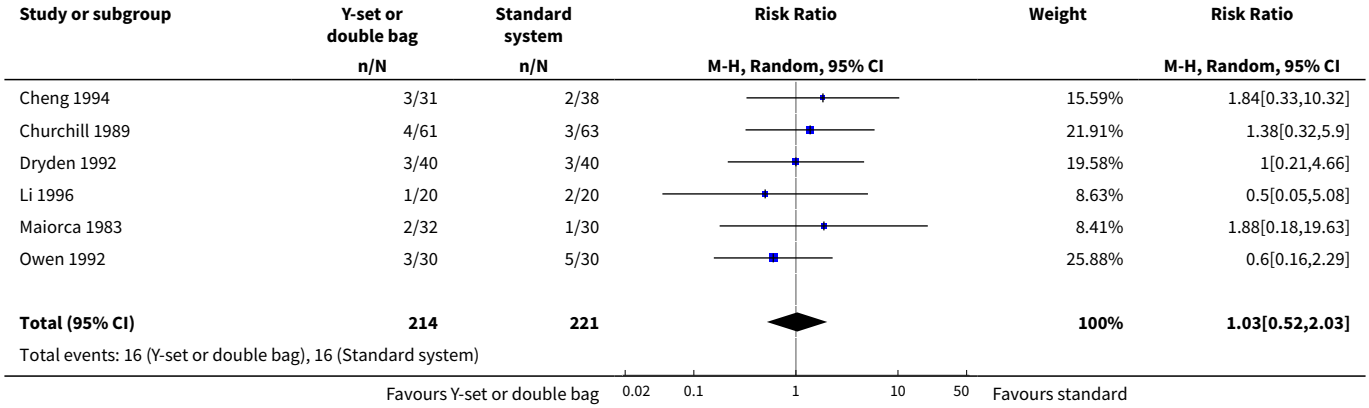
Analysis 3.8. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 8 Number of patients hospitalised (all cause).

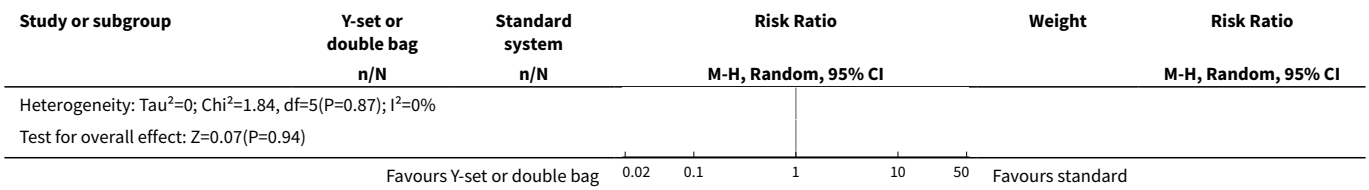


Analysis 3.9. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 9 Number of patients hospitalised (peritonitis).



Analysis 3.10. Comparison 3 Y-set or double bag systems versus standard systems, Outcome 10 All-cause mortality.

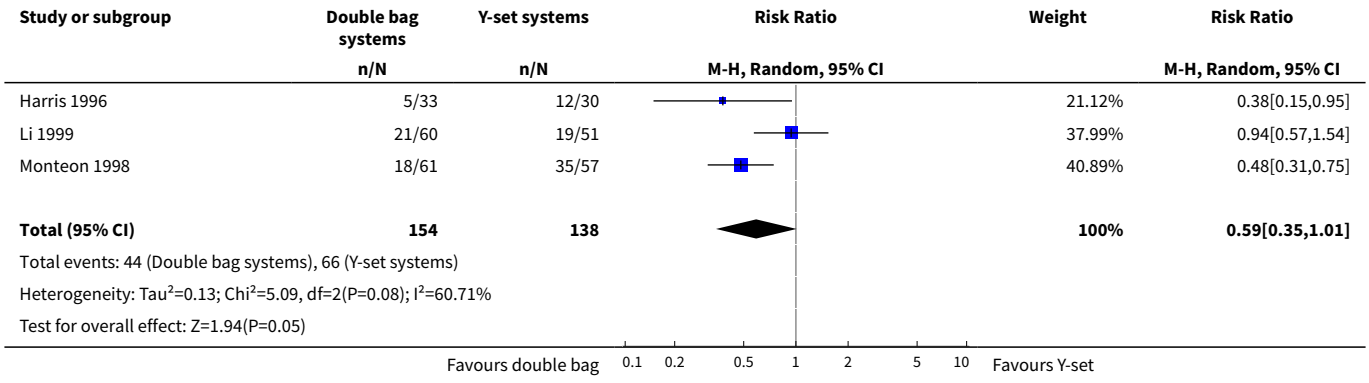




Comparison 4. Double bag systems versus Y-set systems

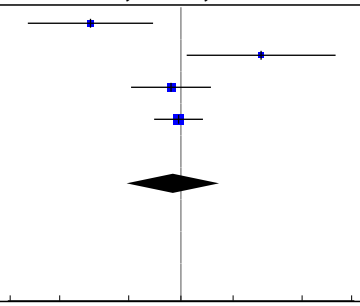
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of patients with peritonitis	3	292	Risk Ratio (M-H, Random, 95% CI)	0.59 [0.35, 1.01]
2 Peritonitis rate	4	4319	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.49, 1.66]
3 Exit-site/tunnel infection rate	3	2665	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.52, 2.06]
4 Number of patients switched to HD	2	145	Risk Ratio (M-H, Random, 95% CI)	0.30 [0.03, 3.10]
5 Number of patients no longer on allocated treatment for whatever reason	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
6 Number of patients who had CAPD catheter removed	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
7 All-cause mortality	2	193	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.25, 3.43]

Analysis 4.1. Comparison 4 Double bag systems versus Y-set systems, Outcome 1 Number of patients with peritonitis.



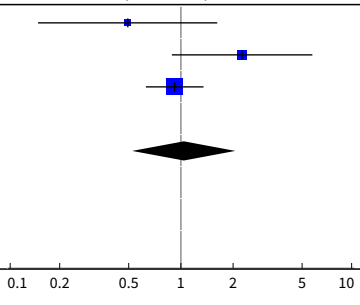
Analysis 4.2. Comparison 4 Double bag systems versus Y-set systems, Outcome 2 Peritonitis rate.

Study or subgroup	Double bag systems n/N	Y-set systems n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Harris 1996	7/326	23/322		21.43%	0.3[0.13,0.69]
Kiernan 1995	15/176	5/170		18.41%	2.9[1.08,7.8]
Li 1999	28/937	25/734		27.97%	0.88[0.52,1.49]
Monteon 1998	81/983	57/671		32.19%	0.97[0.7,1.34]
Total (95% CI)	**2422**	**1897**		**100%**	**0.9[0.49,1.66]**
Total events: 131 (Double bag systems), 110 (Y-set systems)					
Heterogeneity: Tau^2=0.28; Chi^2=12.24, df=3(P=0.01); I^2=75.49%					
Test for overall effect: Z=0.35(P=0.73)					



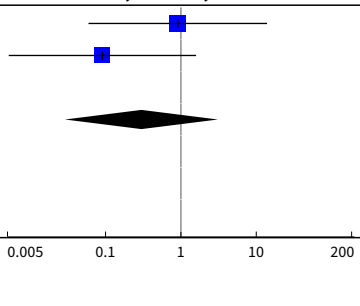
Analysis 4.3. Comparison 4 Double bag systems versus Y-set systems, Outcome 3 Exit-site/tunnel infection rate.

Study or subgroup	Double bag systems n/N	Y-set systems n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Harris 1996	4/326	8/322		21.3%	0.49[0.15,1.62]
Kiernan 1995	14/176	6/170		28.33%	2.25[0.89,5.73]
Li 1999	54/937	46/734		50.37%	0.92[0.63,1.35]
Total (95% CI)	**1439**	**1226**		**100%**	**1.04[0.52,2.06]**
Total events: 72 (Double bag systems), 60 (Y-set systems)					
Heterogeneity: Tau^2=0.2; Chi^2=4.44, df=2(P=0.11); I^2=54.99%					
Test for overall effect: Z=0.11(P=0.91)					



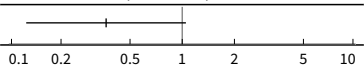
Analysis 4.4. Comparison 4 Double bag systems versus Y-set systems, Outcome 4 Number of patients switched to HD.

Study or subgroup	Double bag systems n/N	Y-set systems n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Harris 1996	1/33	1/30		51.74%	0.91[0.06,13.9]
Kiernan 1995	0/41	5/41		48.26%	0.09[0.01,1.59]
Total (95% CI)	**74**	**71**		**100%**	**0.3[0.03,3.1]**
Total events: 1 (Double bag systems), 6 (Y-set systems)					
Heterogeneity: Tau^2=0.81; Chi^2=1.4, df=1(P=0.24); I^2=28.59%					
Test for overall effect: Z=1.01(P=0.31)					



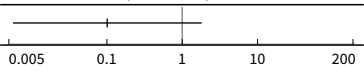
Analysis 4.5. Comparison 4 Double bag systems versus Y-set systems, Outcome 5 Number of patients no longer on allocated treatment for whatever reason.

Study or subgroup	Double bag systems n/N	Y-set systems n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Kiernan 1995	4/41	11/41		0.36[0.13,1.05]



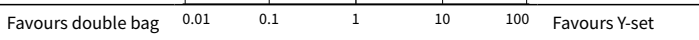
Analysis 4.6. Comparison 4 Double bag systems versus Y-set systems, Outcome 6 Number of patients who had CAPD catheter removed.

Study or subgroup	Double bag systems n/N	Y-set systems n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Harris 1996	0/33	4/30		0.1[0.01,1.81]



Analysis 4.7. Comparison 4 Double bag systems versus Y-set systems, Outcome 7 All-cause mortality.

Study or subgroup	Double bag systems n/N	Y-set systems n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Kiernan 1995	0/41	1/41		17.28%	0.33[0.01,7.95]
Li 1999	4/60	3/51		82.72%	1.13[0.27,4.83]
Total (95% CI)	**101**	**92**		**100%**	**0.92[0.25,3.43]**
Total events: 4 (Double bag systems), 4 (Y-set systems)					
Heterogeneity: Tau^2=0; Chi^2=0.48, df=1(P=0.49); I^2=0%					
Test for overall effect: Z=0.13(P=0.9)					



ADDITIONAL TABLES

Table 1. Number of patient-months on CAPD per episode of peritonitis

Study	Double bag systems	Y-set systems	Standard systems
Cheng 1994	--	30.8	21.5
Churchill 1989	--	21.53	9.93
Li 1996	--	17.0	11.4
Lindholm 1988	--	22.0	8.0
Maiorca 1983	--	33.0	11.3
Owen 1992	--	13.4	4.9

Table 1. Number of patient-months on CAPD per episode of peritonitis *(Continued)*

Rottembourg 1987	--	23.0	12.3
Dryden 1992	25.0	--	9.7
Monteon 1998	24.8	11.8	6.1
Harris 1996	46.4	14.0	--
Kiernan 1995	33.9	11.7	--
Li 1999	33.5	29.4	--

Table 2. Number of patient-months on CAPD per episode of exit-site infection

Study	Double bag systems	Y-set systems	Standard systems
Cheng 1994	--	14.9	16.4
Li 1996	--	26.4	21.6
Kiernan 1995	28.3	12.5	--
Li 1999	17.4	16.0	--

APPENDICES

Appendix 1. Electronic search strategies

Database	Search terms
CENTRAL	#1 ("Y" near/2 set):ti,ab,kw
	#2 (y-tub*):ti,ab,kw
	#3 (y-connect* or (y near/1 connect*)):ti,ab,kw
	#4 (disconnect* near/2 system*):ti,ab,kw
	#5 (twin near/3 bag*):ti,ab,kw
	#6 (double near/3 bag*):ti,ab,kw
	#7 "O-set":ti,ab,kw
	#8 conventional:ti,ab,kw
	#9 spike*:ti,ab,kw
	#10 b-set:ti,ab,kw
	#11 {or #1-#10}
	#12 "continuous ambulatory peritoneal dialysis":ti,ab,kw

(Continued)

	#13 CAPD:ti,ab,kw #14 peritonitis:ti,ab,kw #15 {or #12-#14} #16 #11 and #15
MEDLINE	1. (disconnect* adj2 system*).tw. 2. (twin adj3 bag*).tw. 3. conventional.tw. 4. spike*.tw. 5. b-set.tw. 6. (y adj2 set).tw. 7. y-connect*.tw. 8. o-set.tw. 9. o-system.tw. 10.(double adj3 bag*).tw. 11.or/1-10 12.Peritoneal Dialysis, Continuous Ambulatory/ 13.continuous ambulatory peritoneal dialysis.tw. 14.CAPD.tw. 15.peritonitis.mp. 16.or/12-15 17.and/11,16
EMBASE	1. (disconnect* adj2 system*).tw. 2. (twin adj3 bag*).tw. 3. conventional.tw. 4. spike*.tw. 5. b-set.tw. 6. (y adj2 set).tw. 7. y-connect*.tw. 8. o-set.tw. 9. o-system.tw. 10.(double adj3 bag*).tw. 11.or/1-10 12.continuous ambulatory peritoneal dialysis/ 13.CAPD.tw. 14.continuous ambulatory peritoneal dialysis.tw. 15.peritonitis.mp. 16.or/12-15 17.and/11,16

WHAT'S NEW

Date	Event	Description
26 September 2016	Amended	Minor edit to included and excluded studies

Date	Event	Description
22 September 2016	Review declared as stable	There have been no new or ongoing studies since 1999, therefore this review is no longer being updated. Correa-Rotter 1997, listed as awaiting assessment has now been excluded

HISTORY

Protocol first published: Issue 2, 2001
Review first published: Issue 2, 2001

Date	Event	Description
25 November 2013	New citation required but conclusions have not changed	Our conclusions remained unchanged
25 November 2013	New search has been performed	New search performed. In this 2013 updated review, we excluded six new trials (Bailie 1990; Burkart 1990; de Fijter 1994; Lee 1997; Tan 2005; Wong 2006); one is awaiting classification (Correa-Rotter 1997a).
29 September 2008	Amended	Converted to new review format.
20 November 2005	Amended	Searched for new trials, none identified

CONTRIBUTIONS OF AUTHORS

- Study conception (including funding): MacLeod A, Grant A , Daly C, Donaldson C, Campbell M, Khan I, Lawrence P
- Protocol development: Campbell M, Cody J, Daly C, Donaldson C, Grant A, Vale L, Lawrence P, MacLeod A, Wallace S, Khan I
- Literature search: Wallace S, Daly C, Lawrence P, Cody J, Khan I, Vale L, MacLeod A
- Data extraction and analysis: Daly C, Campbell M, Khan I, Cody J
- Writing of draft report: Daly C
- Updating the review: Strippoli GFM (2004)
- Editorial role and agreement of final manuscript: Campbell M, Cody J, Daly C, Donaldson C, Grant A, Vale L, Lawrence P, MacLeod A, Wallace S, Khan I

DECLARATIONS OF INTEREST

Sheila Wallace is a Trials Search Co-ordinator for the Cochrane Incontinence Review Group, whose single largest funder is the UK National Institute for Health Research (NIHR). The exploratory meeting to set up the Cochrane Incontinence Review Group was funded by Zeneca Pharmaceuticals in 1995.

Following completion of this review, an unrestricted educational grant from Janssen Cilag funded a further six systematic reviews related to ESKD and erythropoietin.

SOURCES OF SUPPORT

Internal sources

- University of Aberdeen, UK.
- Health Services Research Unit, UK.
- Health Economics Research Unit, UK.

External sources

- NHS Executive Research and Development Programme, UK.

NOTES

There have been no new or ongoing studies since 1999, therefore this review is no longer being updated. Correa-Rotter 1997, listed as awaiting assessment has now been excluded.

INDEX TERMS

Medical Subject Headings (MeSH)

Equipment Design; Kidney Failure, Chronic [*therapy]; Peritoneal Dialysis, Continuous Ambulatory [adverse effects] [*instrumentation] [methods]; Peritonitis [etiology] [*prevention & control]; Randomized Controlled Trials as Topic

MeSH check words

Humans