

Supplemental Data

CONSORT Checklist

Supplement Figure 1. Schematic of the PEARL-HD Protocol. HD1 HD2 HD3 first, second and third hemodialysis treatment of the week. K times that serum potassium measurements performed. CCM Continuous cardiac monitor period.

Supplement Table 1. Continuous cardiac monitors study participants, Week 0. PVC premature ventricular contraction; VT ventricular tachycardia.

Supplement Table 2. Adverse events of PEARL-HD participants

Supplemental Table 3. Electrolyte concentrations and ultrafiltration volumes in study participants, Week 4



CONSORT 2010 checklist of information to include when reporting a randomised trial*

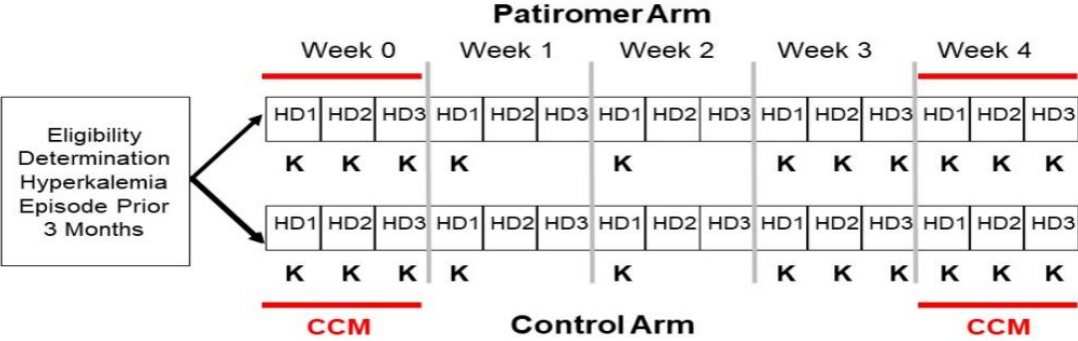
Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	9
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	N/A

		assessing outcomes) and how	
Statistical methods	11b	If relevant, description of the similarity of interventions	N/A
	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	8
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Fig 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-10
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Supp Table 2
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14-15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	21

Citation: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Medicine. 2010;8:18. © 2010 Schulz et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/2.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

Supplement Figure 1.



Supplement Table 1.

	Drug (N=16)	Control (N=15)	Overall (N=31)
PVC			
>1000/24h	3 (18.8%)	2 (13.3%)	5 (16.1%)
>500/24h	1 (6.3%)	0 (0%)	1 (3.2%)
<=500/24h	11 (68.8%)	10 (66.7%)	21 (67.7%)
Missing	1 (6.3%)	3 (20.0%)	4 (12.9%)
Nonsustained VT			
Yes	2 (12.5%)	2 (13.3%)	4 (12.9%)
No	14 (87.5%)	13 (86.7%)	27 (87.1%)
Atrial Fibrillation			
Yes	2 (12.5%)	2 (13.3%)	4 (12.9%)
No	14 (87.5%)	13 (86.7%)	27 (87.1%)
Bradycardia			
Yes	0 (0%)	0 (0%)	0 (0%)
No	16 (100%)	15 (100%)	31 (100%)
Any arrhythmia			
Yes	5 (31.3%)	5 (33.3%)	10 (32.3%)
No	11 (68.8%)	10 (66.7%)	21 (67.7%)

Supplement Table 2.

Treatment Group	Event	Seriousness	Relatedness to study procedures and interventions
Patiromer	hospitalization for new vascular access	Serious event	Not related
	same day surgery to create upper extremity arteriovenous fistula	Serious event	Not related
	bloody stools and diarrhea	Serious event	Not related
	severe heart burn	Non-serious event	Probable
	parasthesias	Non-serious event	Possible
	constipation	Non-serious event	Possible
	itching	Non-serious event	Doubtful
	emergency room visit due to shortness of breath	Non-serious event	Not related
	voiding blood	Non-serious event	Not related
Control	Hospitalization for amputation	Serious event	Not related
	skin sensitivity to Holter Patch	Non-serious event	Probable
	scabies	Non-serious event	Not related
	pain from permcath placement	Non-serious event	Not related
	creation of upper extremity arteriovenous fistula	Non-serious event	Not related
	arrhythmia (Atrial Fibrillation)	Non-serious event	Not related
	boil under left arm	Non-serious event	Not related

Supplement Table 3.

	Overall (N=30)	Control (N=14)	Drug (N=16)
Phosphorus, mg/dl	6.1(4.6,7)	6.25(4.95,7.225)	6(3.5,6.95)
Magnesium, mg/dl	2.3(2.1,2.4)	2.3(2.2,2.4)	2.2(1.95,2.4)
Calcium, mg/dl	9(8.475,9.375)	9.1(8.55,9.4)	8.8(8.55,9.3)
Carbon Dioxide, mmol/L	20(18,22)	20(18.5,21)	20(18,22)
Albumin, g/dl	4.1(4,4.3)	4.15(4.1,4.275)	4.1(3.7,4.4)
Chloride, mmol/l	98(96,99)	98(96.5,99)	98(96,98.5)
Sodium, mmol/l	139.5(137.25,141)	140(137.5,140)	139(137.5,141)
Ultrafiltration Volume, L	2.4(1.73, 3.38)	1.97(1.70, 3.08)	2.65(1.91, 3.53)

Median and Q1, Q3 were reported for each variable. Electrolyte data were collected from week 4, ultrafiltration volumes collected week 3 and week 4.