

## Supplementary material

### Supplementary File Legends

#### Supplementary File A. CONSORT checklist. Source: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT

2010 Statement: updated guidelines for reporting parallel group randomised trials. *J Clin Epi* 2010; 63(8):834-840.

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>	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)	3 - 4
<b>Background and objectives</b>	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	5
<b>Trial design</b>	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6
	4a	Eligibility criteria for participants	6 - 7
<b>Participants</b>	4b	Settings and locations where the data were collected	6
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
<b>Interventions</b>	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9 - 10
<b>Outcomes</b>	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
	7a	How sample size was determined	10 - 11

## Supplementary material

		NA
		7 - 8
		7 - 8
		7 - 9
		7 - 9
		7 - 9
		NA
		10 - 11
		10 - 11
		Figure 1
		12
		12
		12
		Table 1
		12, Figure 1
		12 - 13
		Figures 2A,B
7b	When applicable, explanation of any interim analyses and stopping guidelines	
8a	Method used to generate the random allocation sequence	
8b	Type of randomisation; details of any restriction (such as blocking and block size)	
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	
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
11b	If relevant, description of the similarity of interventions	
12a	Statistical methods used to compare groups for primary and secondary outcomes	
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
	<b>Results</b>	
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
13b	For each group, losses and exclusions after randomisation, together with reasons	
14a	Dates defining the periods of recruitment and follow-up	
14b	Why the trial ended or was stopped	
15	A table showing baseline demographic and clinical characteristics for each group	
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
Randomisation: Sequence generation Allocation concealment mechanism Implementation		
Blinding		
Statistical methods		
Participant flow (a diagram is strongly recommended)		
Recruitment		
Baseline data		
Numbers analysed		
Outcomes and estimation		

## Supplementary material

17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12 - 13
Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13 - 15, Tables 3,4
Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15
	<b>Discussion</b>	
Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20
Generalisability	21 Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16 - 19
	<b>Other information</b>	
Registration	23 Registration number and name of trial registry	6, NCT02887014 NCT02887014
Protocol	24 Where the full trial protocol can be accessed, if available	
Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	None

## Supplementary material

**Supplementary File B.** Instructions according to allocation group.

### **Intervention Group**

One of study's collaborators visits the patients and/or their relatives before the beginning of the preparation and introduces himself.

He informs that the aim of the study is to evaluate the bowel cleanliness in inpatients undergoing colonoscopy. He highlights that the participation in the study, which is not mandatory, requires only some personal anonymous information and that, regardless of participation or not, patient's care will remain in the same high quality standard of care.

Patients and/or their relatives are encouraged to read carefully the informed consent leaflet, which should be signed before the examination and not to hesitate to contact the study's collaborator for any further information.

**After having signed the consent form, the physician reads slowly and clearly the following text for patients allocated to the intervention group:**

- Adequate bowel preparation allows your doctor to fully examine the bowel mucosa without presence of any stool residue. With adequate bowel preparation, easier detection of lesions (e.g. polyps, inflammation) responsible for your symptoms is achieved.
  - Adequate bowel cleanliness shortens the examination time and makes it safer for the patient and technically easier for the endoscopist.
  - Adequate bowel cleanliness allows the safe and direct excision of lesions (e.g. polyps) detected during colonoscopy. Presence of stool residue in the bowel incommodes the procedure making it less safe.
  - Inadequately prepared bowel could impede your doctor to detect your problem, lengthen the examination time, tend potential discomfort and lead to repetition of the procedure.
- 
- The cathartic (PEG) that you will drink for the bowel preparation is provided as powder for oral solution in sachets. Each sachet should be diluted in 1000ml of water. Please, pay caution with the dilution procedure as it may be difficult to find bottles of 1000ml volume.

## Supplementary material

- You should drink each liter of the PEG solution slowly and in a constant rate, approximately one glass (250ml) of the solution every 20-30 minutes. You can additionally drink the following liquids: water, tea, juices without fruit residual, sprite, coke and coffee, as you wish.
- In order to improve the taste of the PEG solution, you can further dilute it using any of the aforementioned liquids.
- If you feel bloating or nausea decrease the solution's consumption rate.
- Ideally, try to complete PEG-solution's consumption 4-6 hours before the time of the scheduled examination.

On top of these simple, specific verbal instructions, the SOC information was provided by the ward nursing staff, according to local study center practice

### Standard of care Group

One of the study's collaborators visits the patients and/or their relatives just before the beginning of the preparation and introduces himself.

He informs that the aim of the study is to evaluate the bowel cleanliness in inpatients undergoing colonoscopy. He highlights that the participation in the study, which is not mandatory, demands only some personal anonymous information and that, regardless of participation or not, patient's care will remain in the same high quality standard of care.

Patients and/or their relatives are encouraged to carefully read the informed consent leaflet, which should be signed before the examination and not hesitate to contact the study's collaborator for any further information.

**After having signed the consent form, no further information is given apart from the SOC information per study center provided by the ward nursing staff. This included provision of the cathartic (PEG) as powder for oral solution in sachets, instruction to dilute each sachet in 1000ml of water and to drink each liter of the PEG solution.**

## Supplementary material

## Supplementary File C. Simulation model exploring adequate bowel preparation rates in different stratification subject mixes.

Stratification (%); mobilized/bedridden: 60/40 (current study's stratification)	Mobilized, n=180		Bedridden, n=120		Total, n=300		p
	Intervention, 90 (50%)	SOC, 90 (50%)	Intervention, 59 (49.2%)	SOC, 61 (50.8%)	Intervention, 149 (49.7%)	SOC, 151 (50.3%)	
<i>Complete colonoscopy</i>	81 (90%)	80 (88.9%)	48 (81.4%)	52 (85.2%)	129 (86.6%)	132 (87.4%)	
<i>Adequate bowel prep, PP</i>	66/81 (81.5%)	53/80 (66.3%)	24/48 (50%)	29/52 (55.8%)	90/129 (69.8%)	82/132 (62.1%)	0.19
<i>Adequate bowel prep, ITT</i>	66/90 (73.3%)	53/90 (58.9%)	24/59 (40.7%)	29/61 (47.5%)	90/149 (60.4%)	82/151 (54.3)	0.29
Stratification (%); mobilized/bedridden: 70/30	Mobilized, n=210		Bedridden, n=90		Total, n=300		p
	Intervention, 105 (50%)	SOC, 105 (50%)	Intervention, 44 (49.2%)	SOC, 46 (50.8%)	Intervention, 149 (49.7%)	SOC, 151 (50.3%)	
<i>Complete colonoscopy</i>	94 (90%)	93 (88.9%)	36 (81.4%)	39 (85.2%)	130 (87.0%)	132 (87.4%)	
<i>Adequate bowel prep, PP</i>	77/94 (81.9%)	62/93 (66.7%)	18/36 (50%)	22/39 (56.4%)	95/130 (73.1%)	84/132 (63.6%)	0.10
<i>Adequate bowel prep, ITT</i>	77/105 (73.3%)	62/105 (59.1%)	18/44 (40.9%)	22/46 (47.8%)	95/149 (63.7%)	84/151 (55.6%)	0.16
Stratification (%); mobilized/bedridden: 80/20	Mobilized, n=240		Bedridden, n=60		Total, n=300		p
	Intervention, 120 (50%)	SOC, 120 (50%)	Intervention, 29 (49.2%)	SOC, 31 (50.8%)	Intervention, 149 (49.7%)	SOC, 151 (50.3%)	
<i>Complete colonoscopy</i>	108 (90%)	107 (88.9%)	24 (81.4%)	26 (85.2%)	132 (88.5%)	133 (88.1%)	

## Supplementary material

<i>Adequate bowel prep, PP</i>	88/108 (81.5%)	71/107 (66.3%)	12/24 (50%)	16/26 (55.8%)	100/132 (75.7%)	86/133 (64.7%)	0.05
<i>Adequate bowel prep, ITT</i>	88/120 (73.3%)	71/120 (59.2%)	12/29 (41.1%)	16/31 (51.6%)	100/149 (67.1%)	86/151 (56.9)	0.07
<b>Stratification (%); mobilized/bedridden: 90/10</b>	<b>Mobilized, n=270</b>		<b>Bedridden, n=30</b>		<b>Total, n=300</b>		
	Intervention, 135 (50%)	SOC, 135 (50%)	Intervention, 15 (50.0%)	SOC, 15 (50.0%)	Intervention, 150 (50.0%)	SOC, 150 (50.0%)	
<i>Complete colonoscopy</i>	122 (90%)	120 (88.9%)	12 (81.4%)	13 (85.2%)	134 (89.3%)	133 (88.7%)	
<i>Adequate bowel prep</i>	99/122 (81.5%)	80/120 (66.3%)	6/12 (50%)	7/13 (55.8%)	105/134 (78.3%)	87/133 (65.4%)	0.02
<i>Adequate bowel prep, ITT</i>	99/135 (73.3%)	80/135 (59.3%)	6/15 (40%)	7/15 (46.7%)	105/150 (70.0%)	87/150 (58.0%)	0.03