A Randomized Clinical Trial Evaluating Three Low-volume Preparations for Colonoscopy in Outpatients With Inflammatory Bowel Disease: The Eii-prep Trial.

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Research Article

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Abstract

BACKGROUND: Bowel preparation is crucial for colonoscopies in patients with Inflammatory Bowel Disease (IBD). However, data regarding cleansing solutions in this setting are scarce.

AIMS: Our aim was to compare efficacy, safety, and tolerability of three different low-volume preparations in patients with IBD.

METHODS: Single-center, randomized, prescriber- and colonoscopist-blinded clinical trial. IBD outpatients undergoing colonoscopy were randomized 1:1:1 to receive 1 Liter-polyethylene glycol-ascorbate (1L-PEG), 2 Liters-PEG or sodium picosulfate (SP). Primary endpoint was efficacy in terms of percentage of quality cleansing assessed via the Boston Bowel Preparation Scale (BBPS >=6 with segments >=2). Secondary endpoints were efficacy in terms of total high quality cleansing (BBPS 8 or 9), high quality segmental BBPS (>=2) and patients’ tolerability, symptoms, and satisfaction, assessed by questionnaires before and after colonoscopy. Safety was monitored by adverse event reporting, laboratory evaluation at colonoscopy and telephonic follow-up.

RESULTS: 92 patients were included (33 1L-PEG, 28 2L-PEG and 31 SP). No significant differences between preparations were observed in quality or high-quality total BBPS or high-quality segmental BBPS. Complete intake of the solution was higher for SP (p=0.006) and lower for 1L-PEG (p=0.02). Clinically irrelevant hyponatremia was higher in the SP group (p<0.0001). SP instructions were easier to understand from the patient’s point of view (p=0.01). Willingness to retake was higher with SP (p<0.0001) and less for 1L-PEG (p<0.0001). No serious adverse events were reported.

CONCLUSIONS: We observed no differences between PEG-based bowel preparations and SP regarding efficacy in patients with IBD. Complete intake was higher for SP and lower for 1L-PEG. SP and 2L-PEG instructions were better understood and graded, and SP was more likely to be retaken. Willingness to retake was lower for 1L-PEG. No serious adverse events were reported.

Summary

No differences in terms of efficacy were regarded in this clinical trial comparing low-volume preparations for colonoscopy in patients with IBD: however, Sodium Picosulfate is better tolerated and accepted from patient’s point of view. No serious adverse event were reported.

Introduction

Colonoscopy plays the main role in the diagnosis and follow-up of Inflammatory Bowel Disease (IBD) (1). Nonetheless, given its invasive nature and required preparation, patients often report lower acceptability rates when comparing it with other monitoring tools (2). Adequate bowel preparation is critical in the
setting of IBD (3) because it allows performing chromoendoscopy, the gold standard technique to screen for IBD-associated dysplasia/colorectal cancer (4), as well as a correct evaluation of endoscopic activity. In a previous study, patients with IBD reported bowel preparation as the most important reason not to comply with surveillance recommendations (5). Therefore, maximizing adherence to cleansing protocols is of paramount importance.

Low-volume preparations have shown better tolerance when compared with other high-volume solutions (6). However, there is a lack of clinical trials assessing solutions for colonoscopy in patients with IBD, and even official guidelines acknowledge a paucity of data regarding this matter (7). In addition, the majority of cleansing preparations state that these products should be used with caution in patients with “acute IBD” (8)(9)(10), thus giving vague indications that differ from routine clinical practice.

Therefore, our aim was to assess the efficacy, tolerability, and safety of three different low-volume bowel cleansing solutions (2 low-volume PEG-based preparations [1L-PEG and 2L-PEG] and sodium picosulfate [SP]) for colonoscopy in patients with IBD.

Materials And Methods

Study design

This was a single-center, randomized, low-intervention, prescriber- and colonoscopist-blinded clinical trial: EudraCT Number 2018-001402-28, clinicaltrials.gov NCT04411017, Registered 24 July 2019 - Retrospectively registered, https://clinicaltrials.gov/ct2/show/NCT04411017. The trial was performed according to the Declaration of Helsinki (1975) and received approval from the local Ethics Committee (Local code 5224). All patients provided written informed consent.

Patients

Inclusion criteria were outpatients aged 18 and older with an established diagnosis of IBD according to the official guidelines of the European Crohn’s and Colitis Organization. Exclusion criteria were patients with a past history of bowel resection, severe acute IBD flare as an indication for colonoscopy (defined as colonoscopy requested at hospital admission for iv corticosteroids), inadequate preparation in a colonoscopy performed within 12 months prior to enrollment (total Boston Bowel Preparation Scale [BBPS] < 6 or any segment with a BBPS score < 2), patients undergoing scheduled therapeutic colonoscopy (e.g., programmed polypectomy or endoscopic dilation), and pregnancy.

Preparation

Cleansing products used for the trial were 1L-PEG (PleinVue®, Norgine BV; Amsterdam, Netherlands), 2L-PEG (Moviprep®, Norgine BV; Amsterdam, Netherlands), and SP (Citrafleet®, Casen Recordati S.L., Zaragoza, Spain).
All patients were instructed to eat a low-fiber diet 72 h prior to the colonoscopy, followed by liquid diet “ad libitum” the day before the procedure. They were also told to take the solution in a split-dose regimen (half of the solution at 9 pm the day before, and the second half on the day of the colonoscopy, ensuring 3 h of fasting prior to the procedure). Each half of the solution was consumed with 1L of clear liquid for 2L-PEG and SP, and 0.5L for 1L-PEG. Complete time course for the preparation procedures is shown in Fig. 1.

All the procedures were scheduled for the morning shift. To check for compliance, the patients were asked by nurses at admission to the endoscopy unit whether they had followed a split-dose regimen and a clear liquid diet the day before; if not, the colonoscopy was postponed. A pre-colonoscopy questionnaire included 2 items regarding this matter: “Did you follow a low-fiber diet in the previous 72 h?” and “Did you follow a split-dose regimen when taking the solution?”

**Treatment allocation and masking**

From February 2019 to June 2021, eligible patients were randomized 1:1:1 to receive either 1L-PEG, 2L-PEG, or SP. Randomization was conducted using the Excel shuffle sort tool. Allocation was performed by non-medical research staff from the unit (L.G.R) at the screening visit and concealed from all medical staff participating in the trial (including colonoscopists). The patients were not blinded to the study medication.

**Outcomes and assessment**

The primary outcome for the trial was efficacy in terms of percentage of total quality cleansing (%TQC), as assessed via the BBPS (total BBPS >= 6, with all segmental BBPS >= 2). Secondary endpoints were efficacy in terms of percentage of total high-quality cleansing (%THQC, total BBPS 8 or 9), segmental colonic preparation and patient tolerability, safety, and satisfaction, evaluated as follows.

Segmental preparation was assessed by %QC in each colonic segment (segmental BBPS >= 2).

The day of the colonoscopy, patients completed a questionnaire and laboratory tests were performed to check for electrolyte imbalances. Seven days after the colonoscopy, patients were contacted for a remote follow-up.

The pre-colonoscopy questionnaire included items regarding tolerability (“Were you able to take the whole solution?“) and satisfaction (“Were you satisfied with the bowel cleansing protocol?” and “Were the instructions for bowel cleansing easy to understand?“) These items ranged on a scale from 1 to 10. The patient was also asked about symptoms during preparation (“Have you presented with any symptoms during bowel cleansing?” e.g., abdominal pain, vomiting). A blood sample was obtained at the trial colonoscopy to assess basic biochemistry parameters (sodium, potassium, chloride, glucose, creatinine, and glomerular filtration rate).

The post-colonoscopy survey (carried out at telephonic follow-up seven days after index colonoscopy) consisted of the same questions on symptoms, and another question regarding tolerability: whether they
would retake the same solution used for the trial in subsequent colonoscopies ("willingness to retake"), to be answered as yes/no. The complete questionnaires can be found in APPENDIX 1.

All the colonoscopies included in the trial were performed by trained IBD specialists from our local site (C.S.F., E.M.A., M.S.A., M.D.M.A.), and all patients underwent deep sedation monitored by an anesthesiologist.

**Sample size calculation and statistics**

Based on previously reported percentages of adequate preparation with 1L-PEG (68%), 2L-PEG (69%), and SP (56.1%) (11) (12) (13), with an alpha error of 5%, a beta error of 20%, and a 95% confidence interval, the total number of patients required was 44. Assuming a 10% loss to follow-up, the sample size was ultimately estimated at 90 patients.

The quantitative continuous variables with normal distribution were described as means with standard deviation (SD). The Shapiro–Wilk test was used to verify the normality of the sample. The quantitative continuous variables with non-normal distribution were represented as medians with interquartile range. The categorical variables are reported as percentages (%). Comparisons between the quantitative variables was performed using Student’s t test or an analysis of variance when suitable. The qualitative variables were evaluated using the chi-squared test.

The sample size calculation and statistical analysis were conducted using Stata for Mac OS (Stata 16.1; November 2017, Stata Corp LLC, College Station, TX, USA). We considered a p-value of < 0.05 statistically significant.

**Results**

A total of 92 patients were prospectively enrolled: 46 (50%) men and 46 (50%) women, with a mean age of 51.68 years (SD 14.68). A flowchart of the patients is shown in Fig. 2. 44 (47.8%) patients were diagnosed as ulcerative colitis (UC), while 43 (46.7%) were Crohn's disease (CD) patients and 5 (5.5%) were IBD-unclassified. We randomized 33 patients to receive 1L-PEG, whereas 28 were allocated to 2L-PEG and 31 were treated with SP. There were no differences among the 3 groups regarding age, IBD subtype, comorbidities, IBD treatment, low-fiber diet intake, time from finishing preparation to colonoscopy, presence of stenosis, or endoscopic disease activity. Complete baseline characteristics of the study population are shown in Table 1.

Indications for colonoscopy were: evaluation of endoscopic activity in 63 patients (68.4%), dysplasia screening in 24 patients (26%) and enrollment for a clinical trial in 5 patients (5.4%).

**Efficacy**

No significant differences between the groups were found regarding the primary endpoint of % TQC (SP: 87% vs 2L-PEG: 85.74% vs 1L-PEG 84.8%; p = 0.8, 0.97 and 0.83 respectively) nor secondary endpoint of
% THQC (SP: 77.4% vs 2L-PEG 53.5% vs 1L-PEG 63.6%; p = 0.079, 0.12 and 0.81 respectively), with all groups achieving a mean total BBPS of 7.75 (SD 1.57).

In terms of the secondary efficacy endpoint of segmental preparation, the %QC in right-colon BBPS was also comparable among preparations (SP: 93.5% vs 2L-PEG: 89.29% vs 1L-PEG: 87.8%; p = 0.44, 0.84 and 0.57 respectively), with all groups achieving a mean right-colon BBPS of 2.5 (SD 0.73). There were also no differences in %QC in transverse and left-colon BBPS. Complete results are displayed in table 2.

Of note, only 6 (6.5%) patients in the trial presented with an inadequate total bowel preparation score (total BBPS < 6; 3 patients in the 2L-PEG group and 3 patients in the 1L-PEG arm). Nine (9.7%) patients had inadequate right-colon BBPS (segmental BBPS < 2). Two patients with inadequate right-colon BBPS received SP, 3 were treated with 2L-PEG, and 4 were in the 1L-PEG arm. 5 patients (5.4%) scored inadequate transverse-colon BBPS (2 in the 1L-PEG arm and 3 in the 2L-PEG arm), and 3 patients presented with inadequate left-colon BBPS (1 patient treated with SP, 1 with 1L-PEG and 1 received 2L-PEG).

**Tolerability**

When grading complete intake of the solution, SP had the highest values compared with 1L-PEG, which was rated significantly lower: 1L-PEG: 8.62, SD 2.53, p = 0.006; 2L-PEG: 9.59, SD 1.42, p = 0.55; SP: 9.93, SD 0.35, p = 0.02. Looking exclusively at the patients who reported the maximum value (10), 96.8% of patients in the SP group graded the preparation with a 10, while 88.9% of patients in the 2L-PEG group and 71.9% in the 1L-PEG arm also reported intake as a 10; these differences were statistically significant (p = 0.016).

**Symptoms**

No symptoms were reported during preparation by 47 (51%) patients. However, 45 patients (49%) complained of symptoms during the cleansing protocol. Abdominal pain was present in 15 (16.3%) patients, and nausea/vomiting were reported by 22 (23.9%). Eight (8.6%) patients complained of both abdominal pain and nausea/vomiting. Clustering patients by the preparation used, we observed 21 (63.6%) symptomatic patients in the 1L-PEG group, 11 (39.3%) in the 2L-PEG group, and 13 (41.9%) in the SP group. No statistically significant differences were found for pre-colonoscopy symptoms between solutions: chi-squared = 4.85; p = 0.08.

Post-colonoscopy symptoms were experienced by 11 (11.9%) patients: abdominal pain in 3 (3.2%), nausea/vomiting in 1 (1.1%), diarrhea in 6 (6%), and headache in 1 (1.1%). Recording symptoms by presence or absence in the post-colonoscopy period: 2 (2.1%) patients complained in the 1L-PEG group, 5 (5.4%) in the 2L-PEG group, and 4 (4.3%) in the SP group. Again, these differences did not reach statistical significance (chi-squared = 2.19; p = 0.33).

**Satisfaction**
Satisfaction with the solution as rated via pre-colonoscopy survey was 6.1 (SD 2.87) for 1L-PEG (p = 0.05); 7.48 (SD 2.7) for 2L-PEG (p = 0.25); and 7.32 (SD 2.74) for SP (p = 0.38). When patients assessed how easy it was to comply with the colonoscopy preparation instructions, SP was rated higher (SP: 9.64, SD 1.08, p = 0.01) than instructions for 1L-PEG (7.93, SD 2.6, p = 0.0001) and 2L-PEG (9.48, SD 0.84, p = 0.1).

**Willingness to retake**

The patients were significantly more likely to retake the SP preparation (96.7%; p = 0.0001) and were less inclined to retake the 1L-PEG preparation (42.4%; p = 0.0001). 78.5% of the patients in the 2L-PEG group showed a willingness to repeat the preparation, although the differences compared with the other preparations were non-significant (p = 0.33).

**Safety**

Plasma concentrations of sodium were significantly lower in the SP group (138.7, SD 2.19, p < 0.0001). We observed no symptomatic hyponatremias among the patients included in the trial. No other clinically meaningful or statistically significant differences were observed regarding laboratory parameters. The complete biochemical parameters are shown among the results reported in Table 2.

No further adverse events (apart from post-colonoscopy symptoms and biochemical disturbances) were detected at the remote follow-up seven days after the procedure.

**Discussion**

Despite the importance of colonoscopy in IBD, few clinical trials have been performed regarding the efficacy of bowel preparations and split-dose regimens for the procedure in this setting. A study published in 2017 (14) attempted to perform a meta-analysis on this topic, but was only able to include 4 studies, with high heterogeneity and risk of bias, thus preventing the authors from reaching firm conclusions. Only 2 of those studies have been performed in recent years (2015 and 2017) (15) (16): they were both randomized trials and compared large-volume PEG (4L-PEG) with 2L-PEG plus ascorbic acid/bisacodyl; however, they only admitted patients with inactive UC. The 2019 French Multicenter CLEAN study (17) is the largest and most recent study regarding this matter. It found no differences between 4L-PEG vs 2L-PEG and SP regarding colon cleansing, in both CD and UC; and though prospective, its design was observational.

Although recently developed low-volume 1L-PEG (11) is effective in the general setting, specific trials comparing it with other low-volume solutions in the context of IBD are still lacking. Our aim was to shed light on these questions by conducting our trial.

Our data show that bowel preparation measured by the BBPS is equivalent with 1L-PEG, 2L-PEG and SP in patients with IBD: both CD and UC. Trials by Manes et al. (15) and Kim et al. (16) found no differences regarding colon cleansing between 4L-PEG and 2L-PEG; however, differences in design (i.e., use of high-
volume preparations and excluding patients with CD) hindered us from comparing our data. The CLEAN trial (17) found that 2L-PEG and SP were significantly superior (p = 0.0021 and 0.0020, respectively) to 4L-PEG for colon cleansing in all subtypes of IBD. The mean BBPS in the CLEAN study was 7.6 for 2L-PEG and 7.7 for SP; our results numerically favored SP (7.35 for 2L-PEG and 8.09 for SP) but did not reach statistical significance.

The BBPS (18) is a widely used and validated index (19) to assess bowel cleansing. Low-quality scores on the BBPS have been associated with missed colorectal neoplasia (20); e.g., it has been previously reported that inadequate bowel preparation (segmental BBPS of 0 or 1) implies a three-fold higher miss rate for adenomas ≥ 5 mm (21). Although dysplasia in IBD is mainly visible (22), most of the lesions detected by chromoendoscopy tend to be flat or slightly elevated (Paris 0-IIa/0-IIb) (23). Therefore, measuring bowel preparation with a reproducible scale can be a valuable tool to ensure high-quality screening colonoscopies in the context of IBD.

We also assessed the tolerability of the solutions from the patient’s perspective, by asking if complete intake of the solution was possible during preparation. Former studies using 4L-PEG as a comparator for 2L-PEG have reported significantly lower rates of complete intake for 4L-PEG (Kim et al. (16): 59.5% of complete intake for PEG-4L vs 82.9% in the PEG-2L group, p < 0.0001; and Manes et al. (15): 66.7% in 4L-PEG vs 95.3% in 2L-PEG, p = 0.001). Incomplete intake has also been previously linked to low BBPS scores (15). Consequently, we designed our trial to focus exclusively on low-volume preparations that offer a potential advantage in terms of tolerability. Grading of complete intake by patients was high for all the products used in our trial (1L-PEG 8.62, 2L-PEG 9.59, SP 9.93); however, we observed statistically significant differences favoring SP and 2L-PEG over 1L-PEG. These data support using low-volume solutions for colonoscopies in patients with IBD (especially SP), given that they allow complete intake and, in turn, potentially better colon cleansing.

Regarding symptoms, we observed no differences between solutions in the pre- or post-colonoscopy setting, either when assessing the symptoms individually or when grouping data under the corresponding preparation. A higher proportion of patients in the 1L-PEG group experienced pre-colonoscopy symptoms such as vomiting or abdominal pain; we believe this is due to the lower reconstituted volume of 1L-PEG (achieved with an increased ascorbate component, which is administered in the second dose only) (11).

Although the patients receiving SP in our trial were more likely to repeat the same solution in subsequent colonoscopies, 1L-PEG was highly disliked for future procedures; these differences were statistically significant. Our data for SP are in line with data from the CLEAN study (17), which showed greater willingness to repeat the SP solution. To our knowledge, no previous data on willingness to repeat 1L-PEG in the context of IBD have been published. The lower willingness for 1L-PEG is probably due to the previously commented increased ascorbate component, which creates an unpleasant taste.

Global satisfaction on our scale was higher for 2L-PEG and SP, without statistically significant differences, in line with previously reported data that favored the better tolerability profile of these drugs (16)(17). The 1L-PEG solution was rated lower than the rest of the solutions, with almost significant
differences (p = 0.05); we believe this is due to the higher proportion of patients in the 1L-PEG group experiencing pre-colonoscopy symptoms and their lower willingness to retake it.

When patients reported how easy it was to prepare the solution, the SP instructions were rated higher (9.64, SD 1.08, p = 0.01) than instructions for 1L-PEG (7.93, SD 2.6, p = 0.0001) and 2L-PEG (9.48, SD 0.84, p = 0.1). Taking these ratings together with previously noted data for tolerability, we could argue that SP was the easiest to prepare and the best tolerated by the patients recruited for the trial.

Regarding safety, we report no new safety signals regarding any of the preparations studied. Only sodium plasma levels were significantly lower among patients receiving SP in our sample. Weir et al. reported a 2.4-fold increased risk of clinically meaningful hyponatremia in adult patients when prepared with SP for colonoscopy (24). Differences in natremia in our trial were clinically irrelevant: the total sodium numbers reported in the SP group matched normal natremia reference values (25); this is probably because our population was younger (mean age 51.68 years) and less predisposed to adverse events than the sample studied by Weir et al. (24), given that they only admitted patients aged older than 66 years.

Our trial has some strengths and limitations to mention. To our knowledge, this is the most recent randomized clinical trial assessing low-volume bowel preparations in all subtypes of IBD, using novel formulas such as 1L-PEG. All the patients followed a split-dose regimen, unlike previous studies where regimes used were mixed (split-dose and same day) (15)(16)(17). Also, ingestion of a liquid diet the day before the procedure was confirmed by nurses from the endoscopy staff. Adherence to clear liquids on the day before colonoscopy has been previously linked with better bowel cleansing in patients with IBD, allowing better performance of chromoendoscopy (26). Ensured compliance with both the split-dosing and the clear liquid diet could explain the low percentages of inadequate preparation obtained in our trial. Patients were not blinded to the study drug, and the primary endpoint addressing colon cleansing was emphasized along the study protocol and the informed consent; therefore, research participants could have complied better with the protocol, given that they knew beforehand that they were being evaluated in this regard. This Hawthorne effect (27) could have played a significant role in the excellent overall BBPS/low percentages of inadequate cleansing in our trial. Conversely, we could argue that making patients aware of the importance of colon cleansing through trial information improved bowel preparation in our sample. An observational study (28) showed that the use of both verbal and written instructions (compared with instructions only) was associated with better bowel preparation. Data from other studies show that physician-delivered education (through counselling sessions) (29), as well as the addition of a dedicated leaflet of classical instructions (30), result in improved quality of preparation and adherence. The results of our trial suggest that appropriate information is crucial for adequate bowel preparation.

Given that it was a single-center trial, the external validity of our results might be limited. We did not detect differences between these drugs regarding symptoms before and after the procedure, because clinical indexes were not registered at baseline and the trial was not sufficiently powered for quantitative comparisons of low-reported symptoms. Therefore, we also couldn't detect worsening of pre-existent
clinical activity; however, previous relapse rates of up to 12% have been described in UC patients undergoing colonoscopy (31). As the last follow-up visit was 7 days post-colonoscopy, long-term adverse events weren’t evaluated. We did not register mucosal lesions possibly associated with bowel preparation, because they are mainly induced by solutions not used in our clinical trial (sodium phosphate solution) (32).

In conclusion, our randomized clinical trial shows that low-volume preparations, both PEG-based (1L and 2L) and SP, are equally effective regarding bowel preparation as measured by the BBPS in patients with IBD, as well as being safe and tolerated; however, SP appears to be better accepted and easier to comply with from the patients’ point of view. No severe adverse events were reported with any of the preparations used. These data can help to establish firm recommendations regarding preparation for colonoscopy in patients with IBD.

**Abbreviations**

- IBD
- Inflammatory Bowel Disease
- UC
- Ulcerative Colitis
- CD
- Crohn’s Disease
- 1L-PEG
- 1 Liter-polyethylene glycol-ascorbate
- 2L-PEG
- 2 Liters-polyethylene glycol-ascorbate
- 4L-PEG
- 4 Liters-polyethylene glycol-ascorbate
- SP
- Sodium Picosulfate
- BBPS
- Boston Bowel Preparation Scale
- PEG
- Polyethylene glycol
- %TQC
- Percentage of Total Quality Cleansing
- %THQC
- Percentage of Total High-Quality Cleansing
- %QC
- Percentage of Quality Cleansing
- SD
- Standard Deviation
Declarations

- Ethics approval and consent to participate

Ethics approval was sought and obtained prior to the initiation of the study from the Local Ethics Comitee from University Hospital La Paz (Local code 5224). All participants provided written informed consent before their inclusion in the trial.

- Consent to publish

Not applicable

- Data and materials.

Raw data were generated at University Hospital La Paz. Derived data supporting the findings of this study are available from the corresponding author (J.L.R.G.) on request.

- Competing interests

J.L.R.G. has served as a speaker for Janssen and has received financial support for traveling and educational activities from Janssen, Takeda, Pfizer, Ferring, Tillotts Pharma, Faes Farma, Norgine, and Casen. C.S.F. has received financial support for traveling and educational activities or has received fees as a speaker or consultant from Ferring, MSD, Janssen, Takeda, and Tillotts Pharma. E.M.A. has received financial support for traveling and educational activities or has received fees as a speaker or consultant from Ferring, MSD, AbbVie, and Takeda. M.S.A. has served as a speaker for Janssen and has received financial support for traveling and educational activities from Takeda, Janssen, Tillotts Pharma, and Ferring. J.P.C. has received financial support for traveling and educational activities from AbbVie, Janssen, Kern Pharma, Pfizer, MSD, Amgen, Takeda, Ferring, Shire, and Tillotts Pharma. M.D.M.A. has received fees as a speaker, consultant, and advisory member for or has received research funding from MSD, AbbVie, Hospira, Pfizer, Takeda, Janssen, Shire Pharmaceuticals, Tillotts Pharma, and Faes Pharma. Remaining authors do not disclose conflicts of interest.

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- Authors' contributions


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References


Tables

Tables 1 and 2 are available in the Supplementary Files section.

Figures
Figure 1: time course for the preparation procedures

Low fiber diet
72h before colonoscopy

Clear liquid diet ad libitum
24h before colonoscopy

SP (Citrafleet):
1st part: SP-Magnesium citrate 15,08g + 1L clear liquid
2nd part: SP-Magnesium citrate 15,08g + 1L clear liquid

2L-PEG (Moviprep):
1st part: Pouch A + Pouch B + 1L clear liquid
2nd part: Pouch A + Pouch B + 1L clear liquid

2L-PEG:
1st part: Dose 1 + 0,5L clear liquid
2nd part: Dose 2 Sachet 1 + Dose 2 Sachet 2 + 0,5L clear liquid

All preparations administered in a split-dose regime:
1st part 5pm day before colonoscopy
2nd part same morning of colonoscopy, ensuring 3h

Figure 1
See image above for figure legend
FIGURE 2: Flowchart of randomized patients.

See image above for figure legend

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.
• TABLES.pdf
• CONSORT2010Checklist.pdf