Picoprep versus Moviprep.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23520

Source
Nationaal Trial Register

Health condition

colonoscopy, colon cancer screening, bowel preparation

coloscopie, darmkanker screening, darmvoorbereiding

Sponsors and support

Primary sponsor: Academic Medical Centre, University of Amsterdam
Source(s) of monetary or material Support: Ferring Pharmaceuticals

Intervention

Outcome measures

Primary outcome

The primary outcome is the achievement of a good cleansing (Ottawa) score, and quality standards such as the caecal intubation rate, intubation and withdrawal time, polyp detection rate and complications.

Secondary outcome

Preparation tolerance; preparation safety; comparison of the 3 available bowel preparation assessment scales.

Confounders influencing the main outcome and secondary endpoints may be age, gender, the starting time of colonoscopy, BMI, colonic disease (IBD, diverticulosis, stenosis, obstruction, constipation), the presence of disease (diabetes, cirrhosis, CVA, dementia, anemia) and the use medication (calcium channel blockers, tricyclic antidepressants) are studies as well.

Study description

Background summary

In a trial to reduce the patient burden of preparation before colonoscopy, we compared a 4-L macrogol solution with twice 90 ml of sodium phosphate. Doctors preferred the preparation with the 4-L whereas patient prefeerd the small-volume preparation. However, the small-volume preparation appeared not to be safe: calcium, phosphate and potassium levels changed considerably.

Study objective

Colonoscopy is considered the reference standard for detection of colonic neoplasia. Polyp detection is dependent on quality standards including endoscopist and patient related factors. Optimal bowel preparation is associated with lower polyp miss rates and thus is one of the patient related factors. Patients have difficulties to comply with the usual 4 litre bowel preparation. A 2 litre bowel preparation is available but the required additional 2 litres of clear fluids remains a problem. Our hypothesis is that a small-volume bowel preparations (Picoprep twice 150 ml with 3-4 litres clear fluids) is equally effective as Moviprep (twice 1000ml with 2 litres clear fluids) in the quality of bowel preparation and is as safe and equally well or even better tolerated and tolerance.

Study design

Quality of bowel preparation and quality standards once, the day of the colonoscopy. Patient's tolerance via a questionnaire once, at the colonoscopy. Safety twice. by blood measuremnts before taking the preparation and day of the colonscopy.

Intervention

One group receives twice 150 ml of Picoprep and the other group twice 1 litre of Moviprep. Both have to take ample extra clear fluids up to a total of 3-4 litres according to their schedule of bowel preparation and colonoscopy time. Also a 2-day fibre-free diet is recommended.

Contacts

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Eligibility criteria

Inclusion criteria

Outpatients, older than 18 years, with an indication to undergo colonoscopy, who can give informed consent and who are able to have bowel cleansing at home.

Exclusion criteria

Patients with significant gastroparesis or gastric outlet obstruction; ileus; known or suspected bowel obstruction or perforation; severe chronic renal failure (creatinine clearance < 30mL/minute); severe congestive heart failure (AHA class III or IV); toxic colitis or megacolon; pregnant patients or patients giving breastfeeds.
Patients with a subtotal colectomy or a colostomy will be excluded because of insufficient remaining colonic surface to evaluate the effects of bowel cleansing.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2013
Enrollment:	340
Type:	Actual

Ethics review

Positive opinion

Date:	24-04-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37589
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3798

Register	ID
NTR-old	NTR3971
CCMO	NL37970.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37589

Study results

Summary results

Mathus-Vliegen EM, Kemble UM. A prospective randomized blinded comparison of sodium phosphate and polyethylene glycol-electrolyte solution for safe bowel cleansing. Aliment Pharmacol Ther 2006;23:543-52.