

PicoPrep versus KleanPrep: Efficacy and patient satisfaction of bowel preparation products before colonoscopy. A single-blinded randomised trial.

Published: 01-10-2012

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To determine which bowel preparation product is superior in cleansing the colon and in patient satisfaction.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37322

Source

ToetsingOnline

Brief title

Picoprep versus Kleanprep: comparing efficacy and patient satisfaction

Condition

- Other condition

Synonym

bowel preparation before colonoscopy

Health condition

darmreiniging voor coloscopie

Research involving

Human

Sponsors and support

Primary sponsor: Kennemer Gasthuis

Source(s) of monetary or material Support: Wetenschapsbureau Linnaeus Instituut

Intervention

Keyword: bowel preparation, efficacy, patient satisfaction, randomised trial

Outcome measures

Primary outcome

efficacy of cleansing product, measured by how clean the bowel is during inspection, based on an ordinal scale of the Boston Bowel preparation scale.

Secondary outcome

Secondary study outcomes: Patient satisfaction, determined by user convenience and taste. The severity of side effects.

Total inspection time and cecum intubation are also registered.

Study description

Background summary

To visualise the mucosa of the bowel during colonoscopy the bowel has to be empty. Therefore patients drink a bowel preparation product before colonoscopy, which empties the bowel. KleanPrep is the most commonly used bowel preparation product in the Netherlands. The disadvantage is that patients find it hard to use and the taste isn't good. PicoPrep is another registered bowel preparation product. This product has a better patient satisfaction.

Previous research there wasn't a direct comparison of split-dose regimes, the studies were very diverse in design and used subjective outcome measurements for efficacy. So no conclusions can be made yet in the comparison of efficacy between the products.

Study objective

To determine which bowel preparation product is superior in cleansing the colon

and in patient satisfaction.

Study design

Randomised single-blinded single-center research

Intervention

Randomisation between PicoPrep and KleanPrep. KleanPrep is the standard bowel preparation product used in the Kennemer Gasthuis at this moment. Efficacy will be determined using the Boston Bowel Preparation Scale. Patient satisfaction and severity of side effects will be determined using a questionnaire.

Study burden and risks

Participation in this study means almost no extra burden for the patient. Only a short questionnaire has to be filled in by the patient. There are no extra visits to the hospital or extra medical interventions. There are no extra risks for the patient when participating, because the products are registered as safe for use in bowel preparation. There is of course always a chance that people suffer from side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Outpatient patients. Competent patient. Signed informed consent.

Exclusion criteria

Age >80 or < 18 years, serious heart failure (NYHA class > 2), known allergy for bowel preparation products, known serious renal failure (MDRD <30), colorectal surgery in history, known serious constipation (less than three bowel movements a week), ileus, pregnancy/lactation, active inflammatory bowel disease.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	17-12-2012
Enrollment:	170
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	KleanPrep
Generic name:	Macrogol and electrolytes
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	PicoPrep (Picolax, Picosalax)
Generic name:	picosulphate, magnesiumoxide, citric acid
Registration:	Yes - NL intended use

Ethics review

Approved WMO	
Date:	01-10-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO	
Date:	05-12-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-004327-21-NL
CCMO	NL42121.094.12