Effect of low-volume (1L) vs high-volume (2L) bowel preparation on cost-effectiveness and quality of life (RESULT study). A multicenter randomized controlled trial

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The main objectives of this study are:1. The effect of high (2L) vs low (1L) volume bowel preparation on the quality of life of patients undergoing colonoscopy. 2. The cost-effectiveness of low-volume bowel preparation versus high-volume preparation...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON52176

Source
ToetsingOnline

Brief title
RESULT

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
bowel cancer, Colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Investigator initiated studie financieel support door Norgine,Norgine

Intervention

Keyword: bowel preparation, colonoscopy, Colorectal carcinoma, quality of life

Outcome measures

Primary outcome

Main endpoints are BBPS result (total and per segment), and proportion of adequately prepared patients per type of bowel preparation.

Secondary outcome

Secondary endpoints include: the absolute score SF-36 and EQ-5D-5L before and after bowel preparation, and incremental cost-effectiveness ratio (ICER), in terms of costs per QALYs, correlation of the clinical parameters and tolerability to QoL scores, total individual costs, treating physician advised surveillance interval per study arm, and subgroup differences for colonoscopy indication and prior experience with bowel preparation.

Study description

Background summary

Adequate bowel preparation for colonoscopy is paramount for optimal diagnostic accuracy and safety. However, the need for high volumes to clean the colon often makes it difficult for patients to adhere to. Therefore, new ultra-low volume bowel preparation fluids have been developed. Little is known on the impact of these ultra-low volume bowel preparation fluids (1L), compared to high-volume (2L) laxatives on quality of life (QoL) and cost-effectiveness.
This study aims to provide further evidence on the presumed positive effect of ultra-low volume bowel preparation on patients* QoL and cost-effectiveness, in

addition to its already demonstrated positive effect on bowel cleansing for colonoscopy.

Study objective

The main objectives of this study are:
1. The effect of high (2L) vs low (1L) volume bowel preparation on the quality of life of patients undergoing colonoscopy.
2. The cost-effectiveness of low-volume bowel preparation versus high-volume preparation.

Secondary study aims are to compare:
1. The Boston Bowel Preparation Score (BBPS) between low- versus high-volume preparation
2. Subgroup differences for the following predefined subgroups: prior experience with bowel preparation, and colonoscopy indication.
3. Measured change in QoL effect of bowel preparations in general using both treatment groups
4. Correlation of patient reported QoL with clinical parameters and reported bowel preparation tolerability

Study design

This multicenter randomized controlled trial (RCT) will be conducted in four hospitals in the Netherlands. We will use secure web-based questionnaires and invite patients to fill in the questionnaire before starting bowel preparation (baseline, t=0) and within 1 week (t=1) after colonoscopy, to assess the impact of bowel preparation on QoL and explore costs and productivity loss for cost-effectiveness analysis. Data on colonoscopy findings and complications will be retrieved from the patients* medical record.

Intervention

Patients will be randomized during the pre-colonoscopy hospital visit between a specialized low-volume 1-liter bowel preparation fluid (Pleinvue) and an high-volume 2-liter bowel preparation fluid (Moviprep), which are both currently used as bowel preparation for colonoscopy in the Netherlands.

Study burden and risks

There is no direct benefit for patients participating in this study. Risk associated with participation are considered minimal, and are limited to the possibility privacy related issues. Nonetheless, this is considered to be minimal because of the use of pseudonymized data and GDPR compliant databases. In the future, results from this study could possibly benefit many patients undergoing colonoscopy, with the possibility of reducing the need for repeat

colonoscopies and improving patient experience of colonoscopies.

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

• Age > 18 years
• Planned elective colonoscopy for screening or diagnostic indications

Exclusion criteria

• Therapeutic colonoscopy (e.g. endoscopic mucosal resection (EMR)
• History of (sub) total colectomy

• Inflammatory bowel disease (IBD)
• Inpatient status
• Indication for an intensified bowel preparation regime
• Emergency colonoscopy
• Limited Dutch language skills
• Dementia
• Visual impairment
• Commonly accepted contra-indications for non-iso osmotic bowel preparation and ascorbate:
o Glucose-6-phosphate-dehydrogenase (G6PD) deficiency
o (sub)ileus
o Bowel obstruction or perforation
o Acute abdomen
o Gastroparesis
o intolerance for any of the formulations ingredients
o Severe renal insufficiency (creatinine clearance < 30mL/min)
o Congestive heart failure (NYHA III or IV)
o Phenylketonuria

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2022
Enrollment:	470
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Moviprep

Generic name:	Polyethylene glycole with ascorbate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Plenvu
Generic name:	Polyethylene glycole with ascorbate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-02-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-03-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-06-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-08-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2021-004885-36-NL
CCMO	NL79014.091.21

Study results

Date completed: 20-05-2023

Actual enrolment: 467

Summary results
Trial is onging in other countries