A new method for bowel cleansing in patients with a history of poor bowel preparation * A multicenter feasibility study with the Pure-Vu

Published: 18-03-2019
Last updated: 11-04-2024

Objective: The aim of this study is to evaluate if an adequate level of bowel cleansing can be achieved with the Pure-Vu in patients with previous poor bowel preparation (Boston Bowel Preparation Scale [BBPS]

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

Summary

ID

NL-OMON49503

Source
ToetsingOnline

Brief title
Pure-Vu II study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Colorectal neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,MOTUS GI

Intervention

Keyword: Bowel, cleansing, colonoscopy, Mechanical

Outcome measures

Primary outcome

The primary endpoint of the study will be the BBPS-score before and after intra-procedural bowel cleaning with the Pure-Vu.

Secondary outcome

* Total number of colon lesions specified by histology

* Adenoma detection rate

* Cecal intubation rates

* Procedure times (total procedure time, cecal intubation time, withdrawal time, time for washing, time for all other interventions)

* Total amount of water used for washing and total amount of fluids+residual stool removed.

* Patient reported outcomes (level of discomfort during bowel preparation and during colonoscopy on a visual analog scale)

* System usability

* Operator learning curve

* Safety outcomes

Study description

Background summary

Rationale: It is widely acknowledged that the efficacy and safety of colonoscopy depends on the quality of the pre-procedural bowel preparation. Despite its importance, the proportion of colonoscopies with inadequate bowel preparation still ranges from 6.8-33% across studies. A past history of poor bowel preparation is the most important risk factor of inadequate bowel cleansing at the next colonoscopy. (1, 2) Evidence to recommend a specific bowel cleansing regimen in these patients is currently lacking. (3) Mostly, patients with previous bowel preparation are advised to drink more oral purgatives, which is very difficult and unpleasant for patients and therefore often fails.
The aim of this study is to evaluate if an intra-procedural bowel cleaning device, the Pure-VuTM system (Tirat Carmel, Israel) can be used to achieve an adequate level of bowel cleansing in patients with previous poor bowel preparation.

Study objective

Objective: The aim of this study is to evaluate if an adequate level of bowel cleansing can be achieved with the Pure-Vu in patients with previous poor bowel preparation (Boston Bowel Preparation Scale [BBPS]<6).

Study design

We will perform an international multicenter colonoscopy trial. Adult patients with previous poor bowel preparation (BBPS<6) will be invited to participate in our study (n=40). Patients willing to participate will receive a limited bowel preparation (2-days of dietary restrictions + 2x 10 mg bisacodyl + 150ml picoprep) followed by intra-procedural bowel cleansing with the Pure-Vu. The BBPS will be assessed before and after segmental washing by the endoscopist who performs the procedure and later by an independent endoscopist (photos).

Intervention

Pure-Vu

Study burden and risks

Colonoscopy is a commonly performed procedure and the overall serious adverse event (SAE) rate is low, around 2.8 per 1000 colonoscopies. The risk of adverse events (AE) with the Pure-Vu are believed to be equivalent to conventional colonoscopy, including bleeding and perforation risks. [unpublished results; publishing date 01/2019 in endoscopy] Participation in this study could potentially benefit colonoscopy patients because the Pure-Vu is expected to improve the quality of colonoscopy. Inadequate bowel cleansing may be prevented by the Pure-Vu. Inadequate bowel cleansing is associated with lower adenoma detection rates (ADR), lower completion rates, longer procedure

times, more complications and a higher need for repeat procedures.(4, 5) In addition, Pure-Vu reduces the reliance on patients pre-procedural bowel preparation which is often considered the most deterrent part of colonoscopy by patients.

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

Inclusion criteria: 18 years or older, referred for colonoscopy, previous inadequate bowel preparation

Exclusion criteria

Exclusion criteria; previous colon resection, previous colorectal cancer, colitis, lower gastrointestinal bleeding with hemodynamic instability, ASA>3, insufficiently corrected anticoagulation disorders, inability to provide informed consent.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2021
Enrollment:	22
Type:	Actual

Medical products/devices used

Generic name:	Pure-Vu
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-03-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-12-2020

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
CCMO	NL66613.091.18

Study results

Date completed:	19-04-2022
Actual enrolment:	22

Summary results
Trial is onging in other countries