A randomized clinical trial to evaluate the efficacy of polyethylene glycol vs psyllium fiber to prevent rebleeding in patients hospitalized with bleeding diverticular disease.

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To evaluate the efficacy of laxatives (polyethylene glycol) versus supplementation of fibers on the incidence of rebleeding in patients hospitalized for colonic diverticular bleeding.

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON52735

Source
ToetsingOnline

Brief title
Prevention of rebleeding in diverticular disease.

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Bleeding Diverticular disease

Research involving
Human

Sponsors and support

Primary sponsor: Elisabeth-Tweesteden ziekenhuis
Source(s) of monetary or material Support: stichting Innovatie en Kwaliteit Maag;Darm-;Leverziekten

Intervention

Keyword: Bleeding Diverticular disease

Outcome measures

Primary outcome

The primary endpoint of this study is the difference in incidence of rebleeding measured by preformatted questionnaire and clinical data between the polyethylene glycol vs psyllium fiber group.

Secondary outcome

The secondary endpoints of the study are the differences in quality of live indicated by the EuroQol questionnaire, stool frequency and - consistency measured by the Bristol Stool Scale and diverticular disease activity measured by standard clinical and laboratory assessments.

Study description

Background summary

Colonic diverticular bleeding is one of the most common causes of lower gastrointestinal bleeding. The results of a previous studies showed that repeated rebleeding occurs in approximately 10-20% within the first year. No consensus exists as to the best treatment to prevent rebleeding. Treatment options range from lifestyle advise such as increased intake of dietary fiber, supplementation of fibers or laxatives.

Study objective

To evaluate the efficacy of laxatives (polyethylene glycol) versus

supplementation of fibers on the incidence of rebleeding in patients hospitalized for colonic diverticular bleeding.

Study design

Single-center, randomized clinical trial to evaluate the efficacy of polyethylene glycol versus psyllium fiber twice daily on the incidence of rebleeding in patients who have been hospitalized for bleeding diverticular disease. During the follow-up, the physician might adjust the dosage of polyethylene glycol or psyllium fiber based on stool frequency and consistency.

Intervention

Group A: polyethylene glycol (OTC) twice daily, for the period of 12 weeks.
Group B: psyllium fiber (OTC) twice daily, for the period of 12 weeks.

Study burden and risks

Subjects will be asked to fill out the above mentioned questionnaires as indicated by the table of assessments at the start of the study and at each regular outpatient clinic visit at 6 and 12 weeks. Furthermore, daily practice laboratory assessments will be collected during the study, as being part of the regular outpatient clinic visits of the patients. Polyethylene glycol and psyllium fiber have few side effects, if they occur tend to be mild.

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

Patients between the ages of 18 or older.
Patients who are hospitalized for bleeding diverticular disease in het ETZ.
Patients with diverticular disease based on colonoscopy, sigmoïdscopy or CT-scan <5 years

Exclusion criteria

Other bleeding diseases of the colon requiring medicinal treatment such as IBD or infection
Surgical treatment following initial episode of bleeding diverticular disease.
Patients using polyethylene glycol or psyllium fiber regularly, more than twice daily.
Patients who are pregnant, lactating or planning pregnancy while enrolled in the study.
Patients who are unsuitable for inclusion in the study in the opinion of the investigator for any reason that may compromise the subject*s safety or confound data interpretation

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Single blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-05-2022
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO Date:	13-07-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-12-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29193
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL71286.028.19

Study results

Date completed:	03-12-2024
Actual enrolment:	47

Summary results
Trial ended prematurely