PREVENTION

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29193

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Colonic diverticular bleeding

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Evaluation of the efficacy of polyethylene glycol versus psyllium fiber in a randomized controlled trial to prevent rebleeding and readmission in patients hospitalized for colonic diverticular bleeding.

Secondary outcome

Assessment of the effect of polyethylene glycol versus psyllium fiber on 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 previous studies show 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.
This study aims to evaluate the efficacy of laxatives (polyethylene glycol) versus supplementation of fibers on the incidence of rebleeding in patients hospitalized for colonic diverticula bleeding.
Single-center, randomized clinical trial.

Study objective

Decreasing the intraluminal pressure has a inhibiting effect on the rebleeding incidence.

Study design

Screening period (-2 days, Visit 0), Week 0 (visit 1), Week 6 (Visit 2), Week 12 (visit 3).

Intervention

Polyethylene glycol or Psyllium fiber

Contacts

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Eligibility criteria

Inclusion criteria

- Patients between the ages of 18 and 85 years old;
- Patients who are hospitalized for bleeding diverticular disease in the Elisabeth-Tweesteden Ziekenhuis (ETZ);
- Patients with diverticular disease based on colonoscopy <5 years.

Exclusion criteria

- Other bleeding diseases of the colon requiring medicinal treatment such as IBD or infection;
- Patients hypersensitive to macrogol or psyllium;
- 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 type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-05-2021

Enrollment:	260
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-05-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52735
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9454
CCMO	NL71286.028.19
OMON	NL-OMON52735

Study results