

# PREVENTION

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	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 life 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 advice 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 an 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

### Public

Elisabeth-Tweesteden Ziekenhuis  
Yara van Knippenberg

+31132218466

### Scientific

Elisabeth-Tweesteden Ziekenhuis  
Yara van Knippenberg

## 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