Effectiveness and cost-effectiveness of rubber band ligation versus sutured mucopexy versus haemorrhoidectomy in patients with recurrent haemorrhoidal disease: a multicentre randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON55344

Source
ToetsingOnline

Brief title
The Napoleon Trial

Condition

- Anal and rectal conditions NEC

Synonym
haemorrhoids

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw Doelmatigheid Onderzoek

Intervention

Keyword: haemorrhoidal disease, patient-reported outcome measures, recurrence, rubber band ligation

Outcome measures

Primary outcome

Primary outcomes are (1) recurrence of HD over 1 year and (2) patient-reported

symptoms assessed after 12 months.

Secondary outcome

Secondary outcome variables are early and late complications, impact of

symptoms on daily activities, patient satisfaction with treatment,

health-related quality of life, costs, cost-effectiveness and budget-impact.

Study description

Background summary

Haemorrhoidal disease (HD) is the most common type of anorectal complaint in the Netherlands, with an annual prevalence of
10% in general practice. There is level I evidence in literature that the first management step of HD is basic treatment,
including laxatives and high fibre diet. The general practitioner usually offers basic treatment. If basic treatment fails
patients are referred to the hospital. About 50.000 patients are referred to a hospital for HD in the Netherlands annually. The
next treatment modality after basic treatment in case of persistent symptoms is rubber band ligation (RBL), which can be
repeated if necessary. RBL is an easy, cheap and outpatient-based procedure. Thirty per cent of the patients, approximately

15.000 patients a year, develop recurrent symptoms after basic treatment and repeat RBL. There is currently no consensus
and a lack of evidence regarding the best treatment option for these patients having recurrent HD: continuing RBL or a surgical
intervention. Literature indicates that haemorrhoidectomy is the surgical treatment of choice based on outcomes like recurrence
rate. The major drawback of this technique is that it is very painful and more costly compared to RBL. A relatively novel,
but regular surgical alternative is the sutured mucopexy. Although hospital costs of sutured mucopexy are comparable to
haemorrhoidectomy, the operation is less painful and requires less recuperation time. The recurrence rate of sutured mucopexy
is ranked between that of RBL and haemorrhoidectomy.
Up till now, trials were mostly powered on traditional outcomes like recurrence, a definition that differs widely between studies.
To improve transparency between studies and facilitate the ability to compare and combine (future) studies, our research group
developed a European Society of Coloproctology (ESCP) Core Outcome Set (COS) for HD. This international COS for HD
selected *patient-reported symptoms* as primary outcome. Additionally, we recently developed a patient reported symptom
score for HD: the PROM-HISS. This PROM is based on most cited symptoms in literature and patient interviews. The patient
advisory board (PAB) of this project underlines the clinical relevance of this PROM. As the PROM-HISS has not yet been used
in other studies and has to be validated, we will additionally use patient-reported symptoms assessed by the PROM-HISS, next
to recurrence, as primary outcome in this trial.

Study objective

The primary objective of this RCT is to compare the effectiveness of RBL, sutured mucopexy and haemorrhoidectomy regarding recurrence and patient-reported symptoms for recurrent grade 2 and 3 HD after at least 2 previous RBL treatments. Secondary objectives are to compare RBL, sutured mucopexy and haemorrhoidectomy for recurrent grade 2 and 3 HD after previous RBL treatments in terms of early and late complications, impact of symptoms on daily activities, patient satisfaction with treatment, health-related quality of life, costs and cost-effectiveness, and budget impact.

Study design

Dutch prospective multicentre randomized controlled trial. This RCT will take place in 20 Dutch medical centers.

Intervention

Rubber band ligation versus sutured mucopexy versus haemorrhoidectomy. All three interventions are part of Dutch usual care, and serve as each other*s control.

Study burden and risks

For this study, patients are asked to take part in a study comparing treatment of haemorrhoids by rubber band ligation, sutured mucopexy and haemorrhoidectomy. Patients will not have extra hospital visits. Patients will be asked to complete online questionnaires on 4 different occasions (4 x 20 minutes): at baseline, at 1 and 6 weeks and 12 months after the intervention. The content includes general and disease specific QoL, and health related costs. We do not expect any adverse reactions or events in respect to participation in the study because all three procedures are considered standard care.
Since we compare a non-surgical intervention with 2 surgical interventions, this may place both surgical groups in a less favourable position. However, all three interventions are usual care and are accepted treatments in the arsenal of options for haemorrhoidal disease 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

Haemorrhoidal disease grade 2 and 3 (Goligher classification)
18 years of age and older
at least 2 or more rubber band ligations in medical history
sufficient knowledge of the Dutch language, spoken and written
obtained written informed consent

Exclusion criteria

Previous rectal or anal surgery with the exception of rubber band ligation
Patients that have had previous surgery for HD (at any time)
Previous rectal radiation
Pre-existing sphincter injury
Actieve diseases of the colon and rectum (i.e. active IBD/diverticulitis/gastro-intestinal malignancy)
Medically unfit for surgery or for completion of the trial (ASA>III)
Pregnancy
Patients with hypercoagulability disorders
Patients previously randomised to this trial
Patients that are unable or not willing to give full informed consent

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-07-2020
Enrollment:	558
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-03-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-06-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-09-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-01-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-04-2021

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT04101773
CCMO	NL71736.068.19