Haemorrhoidectomy versus rubber bAND ligation in grade III haemorrhoids: HollAND trial

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To establish the best treatment of patients with symptomatic haemorrhoids grade III: haemorrhoidectomy versus rubber band ligation (RBL). Patient bound effectiveness, clinical effectiveness and cost-utility of both treatments is...

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

Summary

ID

NL-OMON24433

Source
Nationaal Trial Register

Brief title
HollAND trial

Condition

- Anal and rectal conditions NEC

Health condition

Haemorrhoids graad III.

Research involving
Human

Sponsors and support

Primary sponsor: Proctos Kliniek Bilthoven

Source(s) of monetary or material Support: ‘Leading the Change’ programma van Stichting Zorgevaluatie (projectnummer 80-85009-98-2001)

Intervention

- Surigical procedure

Explanation

Outcome measures

Primary outcome
Primary outcomes are quality of life measured with the Eq-5d-5L with Dutch rating and recurrence rate measured at 12 months follow-up.

Secondary outcome
Secondary outcomes are: complaint reduction with proctology specific patient-related outcome measure (HSS, PROM, PROMHISS), vaizey score, resumption of work, pain (VAS), complications and recurrence at two years.

Study description

Background summary
Haemorrhoidal disease is one of the most common anorectal disorders which affects nearly half of the general population. Given the current numerous modalities the obvious question which needs to be answered is which treatment is the best. An interesting conclusion from a recent systematic review regarding operative procedures for haemorrhoidal disease is that all procedures have their own advantages and disadvantages. There is a need for evaluating treatment from the patient’s point of view and transparency in surgical and non-surgical treatment outcome. So far there is no sufficiently large trial that meets that demand.

Study objective
To establish the best treatment of patients with symptomatic haemorrhoids grade III: haemorrhoidectomy versus rubber band ligation (RBL). Patient bound effectiveness, clinical effectiveness and cost-utility of both treatments is compared; primary outcome is quality of life

at 24 months measured with the EQ-5D-5L with Dutch rating and recurrence at one year post

procedure. The assumption is that treatment with rubber band ligation is equally effective in

comparison with haemorrhoidectomy in terms of quality of life.

Study design
Multicentre randomized controlled non-inferiority trial with cost-utility analysis.

Two treatment protocols are compared: haemorrhoidectomy and rubber band ligation

Intervention

Rubber band ligation versus haemorrhoidectomy

Study burden and risks
For this study, patients are asked to take part in a study comparing treatment of haemorrhoids

by rubber band ligation and haemorrhoidectomy. Patients will not have extra hospital visits.

Patients will be asked to complete 8 questionnaires on 6 different occasions (6 x 10 minutes):

at baseline, at 1 and 6 weeks and 6, 12 and 24 months after surgery. The content includes

general and disease specific QOL, health related costs, subjective cure and adherence to

therapy. We do not expect any adverse reactions or events in respect to participation in the

study because both procedures are considered standard care.

Contacts

Public
Proctos Kliniek
Justin van Oostendorp
Prof. Bronkhorstlaan 10, gebouw 60-62
3723 MB
Bilthoven
Nederland

0613780223
Scientific
Proctos Kliniek
Justin van Oostendorp
Prof. Bronkhorstlaan 10, gebouw 60-62
3723 MB

Bilthoven
Nederland

0613780223

Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

• Hemorrhoids grade III (Goligher classification) • Age 18 years and older • Sufficient understanding of the Dutch written language (reading and writing)

Exclusion criteria

• Previous rectal or anal surgery with the exception of rubber band ligation • Previous surgery for haemorrhoids (at any time) • More than one injection treatment for haemorrhoids in the past 3 years • More than one rubber band ligation procedure in the past 3 years • Previous rectal radiation • Pre-existing sphincter injury • Inflammatory bowel disease • Medically unfit for surgery or for completion of the trial (ASA>III) • Pregnancy • Hyper-coagulability disorders • Therapy with Warfarin, Clopidogrel or oral anticoagulance • Patients previously randomised to this trial • Not able or willing to provide written informed consent

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	25-11-2019
Enrollment:	360
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	01-08-2019
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 55719
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8020
CCMO	NL69227.018.19
OMON	NL-OMON55719

Study results