Comparison of rubber band ligation and haemorrhoidectomy in patients with symptomatic haemorrhoids, a multicentre, randomized controlled trial and cost-utility analysis

Published: 01-08-2019
Last updated: 21-12-2024

This study investigates the two most commonly performed surgical procedures for treatment of grade III hemorrhoids. It aims to identify the best surgical treatment for this patient group considering quality of life.. Other outcomes measured are...

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

Summary

ID

NL-OMON55719

Source
ToetsingOnline

Brief title
HollAND trial

Condition

- Anal and rectal conditions NEC

Synonym
haemorrhoids

Research involving

Human

Sponsors and support

Primary sponsor: Proctos Kliniek
Source(s) of monetary or material Support: Leading the Change call (zorgverzekeraar)

Intervention

Keyword: cost utility analysis, Haemorrhoidectomy, patient related outcomes, Rubber band ligation

Outcome measures

Primary outcome

Primary outcome measure is quality of life at 12 and 24 months measured with

the EQ-5D-5L with Dutch rating; in-hospital direct and indirect costs (measured

with EQ5D and cost incremental analysis) and out-of-hospital postoperative

costs (measured with EQ5D and cost incremental analysis).

Secondary outcome

Patient-related outcome measures:

complaint reduction (Haemorroid Symptom Score, HSS),

proctology specific validated patient-related outcome measure (PROM)

Vaizey faecal incontinence score

visual analogue scale pain score (VAS)

duration of absence from work

analgesic requirement during the first three days

Clinical outcomes:

Complications

Postoperative bleeding requiring re admittance and/or blood transfusion

Urinary retention requiring catheterisation

Anal fissure

Emergency reoperation

Anal stenosis

Residual anal skintags

Need for further treatment

Duration of surgery

Length of hospital stay

recurrence within one and two years

Study description

Background summary

Haemorrhoidal disease is one of the most common anorectal disorders which affects nearly half of the general population1. In the Dutch population prevalence is 9 per 1,000 patients per year [DIS]. Symptoms vary from blood loss, itching, soiling and prolapse and can be severe having a substantial impact on a patients activities. Haemorrhoids are described most often by the Goligher classification: a universally used classification focusing on the degree of prolapse 2However in a large colonoscopy-based study no significant association could be demonstrated between haemorrhoid grade and haemorrhoid symptoms [Iyer 2004]. Treatment consists initially of conservative measures such as lifestyle advice, diet and toilet behavior 3 In addition, various surgical procedures are possible, of which haemorrhoidectomy is considered the gold standard, an assumption recently confirmed in two British trials [Hubble, Ethos]. The most commonly used, low-invasive procedure is the rubber band ligation (RBL). With better understanding of origin and pathogenesis of haemorrhoids new surgical techniques were developed. 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 4. Therefore items like patient expectations and priorities and costs should be taken into account when deciding which procedure to advice and perform. 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. A recent national survey amongst Dutch surgeons with

expertise in haemorrhoidal disease demonstrated varying practices in treatment of haemorrhoids. A similar survey was conducted in Italy including more than 32000 patients. Although (and maybe because of) the most frequently used treatment modalities differed from the ones in the Dutch study the conclusion is the same: necessity of developing practical (Dutch and European) guidelines for treatment of haemorrhoidal disease 5, 6. Therefore, a well-designed study is essential to compare efficacy and safety of repeated rubber band ligation and haemorrhoidectomy for grade III hemorrhoids in a multicenter randomized setting.

Study objective

This study investigates the two most commonly performed surgical procedures for treatment of grade III hemorrhoids. It aims to identify the best surgical treatment for this patient group considering quality of life.. Other outcomes measured are other patient related outcome measures, clinical outcome andcost utility.. Patients will be followed up for two years.

Study design

The study concerns a randomized, controlled, multicenter trial comparing rubber band ligation with hemorrhoidectomy for treatment of grade III hemorrhoids. Patients will be accrued by all participating clinics. The design involves allocation of all appropriate consecutive patients with symptomatic grade III hemorrhoids to either rubber band ligation or hemorrhoidectomy. After eligibility has been established and patient details noted patients will be randomized to either one of the study groups. Assignment to one of the two groups is not blinded. Randomization is performed by computer and will be done through internet. Data will be analysed on *intention to treat* basis in case patients are not subjected to the randomised treatment modality. Exclusion criteria are former radiotherapy, inflammatory bowel disease and former anal surgery.

Intervention

Rubber band ligation:
Rubber band ligation, first described by Barron, is performed by a suction device that allows a rubber band to be applied at the base of the haemorrhoid via a proctoscope. Maximal suction force used is 40 mmHg. A maximum of 3-4 bands are used per session. This rubber band constricts the blood supply causing it to become ischaemic before being sloughed approximately 1-2 weeks later. The resultant fibrosis reduces any element of haemorrhoidal prolapse that may have been present. No sedation is required for this day-care procedure. Patients are asked to administer an enema 2 hours prior to the procedure. This is a very commonly performed procedure in all participating clinics.

Haemorrhoidectomy:
There are two main excisional procedures currently carried out: open (Milligan and Morgan) and closed (Ferguson). Both have the intention of excising the haemorrhoidal cushions. The procedure is performed under either general or spinal anaesthesia in a day-care setting. Patients were asked to administer an enema 2 hours prior to the procedure.

Study burden and risks

Questionnaires at 6 different time points - baseline, 1,and 6 weeks, 6,12 and 24 months postoperative. (6 x 30 minutes)

Contacts

Public
Proctos Kliniek

prof Bronkhorstlaan 10
Bilthoven 3723MB
NL
Scientific
Proctos Kliniek

prof Bronkhorstlaan 10
Bilthoven 3723MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Haemorroids grade III (Golligher classification)
18 years of age and older
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 haemorrhoids (at any time);
patients that have had more than one injection treatment for haemorrhoids in the past 3 years;
patients that have had more than one rubberband 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
patients with hyper-coagulability disorders
Patients that are unable to give full informed consent
Patients previously randomised to this trial

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-11-2019
Enrollment:	360

Type:	Actual

Ethics review

Approved WMO Date:	01-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	21-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 24433
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69227.018.19