A prospective single-blinded randomized multi-center clinical trial comparing the clinical efficacy and patient acceptability of open selective haemorrhoidopexy with stapled haemorrhoidopexy

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The purpose of this prospective randomised trial is 1) to compare short- and long-term efficacy of open selective haemorrhoidopexy with stapled haemorrhoidopexy; 2) to compare patients satisfaction between open and stapled haemorrhoidopexy.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON39498

Source
ToetsingOnline

Brief title
PILE STOP Study

Condition

- Anal and rectal conditions NEC
- Therapeutic procedures and supportive care NEC

Synonym
haemorrhoids, piles

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Covidien

Intervention

Keyword: haemorrhoid, haemorrhoidopexy, stapler, surgery

Outcome measures

Primary outcome

Primary endpoint is recurrence after two years.

Secondary outcome

Secondary Objectives:

- Postoperative pain (VAS Score)

- Early complications within 6 weeks postoperative: urinary retention,

obstipation, incontinence

- Complaints of urgency, tenesmus, pruritus

- Patient satisfaction (VAS Score)

- Operating time

- Time of hospitalization

- Re-admission to hospital

- Time to return to work

- Late complications: anal stenosis, impaired continence (Wexner Continence

Score), recurrence

- Re-treatment rates

- Need for additional skin tag excision

- Quality of life (SF-36 Health Survey questionnaire)

- Cost effectiveness

Study description

Background summary

Until today, it seems there is no optimal treatment for 3rd, 4th degree and recurrent haemorrhoidal disease. All available treatment modalities have important disadvantages, ranging from significant postoperative pain to high recurrence rates.
Stapled haemorrhoidopexy is a widespread used procedure in case of 3rd degree, selected cases of 4th degree haemorrhoidal disease and in case of recurrence. With this procedure a circular partial resection of the mucosa proximal from the haemorrhoidal tissue is performed. Postoperative pain is significantly less compared to the traditional haemorrhoidectomy. In open haemorrhoidectomy the haemorrhoidal tissue itself is excised, resulting in relatively large wounds in the sensitive perianal area. Another advantage of the stapled haemorrhoidopexy compared with the open haemorrhoidectomy is that the haemorrhoidal tissue is preserved with the stapler technique. Maintenance of haemorrhoidal tissue is important to maintain optimal rectal sensitivity anal continence. However, the stapled haemorrhoidopexy has disadvantages like high costs and - although very rare - has been associated with complications like pelvic abcesses and fistula*s. Therefore, adequate training is mandatory before performing stapled haemorrhoidopexy..
In 2008 Pakravan presented a new technique describing selective haemorrhoidopexy with only sutures. The technique consists of a selective pexy of prolapsing haemorrhoidal tissue without resection of circular flap of mucosa. From this point of view it is very similar to the above mentioned stapled haemorrhoidopexy, with preserving the haemorrhoidal tissue. A considerable advantage of the selective haemorrhoidopexy are the low costs as no special stapling devices are needed for this procedure and the short learning curve. Early results of Pakravan*s technique show good results in regard to postoperative pain, recurrence and continence. Long term results are not available until now.

Study objective

The purpose of this prospective randomised trial is 1) to compare short- and long-term efficacy of open selective haemorrhoidopexy with stapled haemorrhoidopexy; 2) to compare patients satisfaction between open and stapled haemorrhoidopexy.

Study design

The study has a randomized, controlled, single blind, clinical multicenter trial study design.
The study will be conducted by the Department of Surgery of the University Hospital Maastricht in co-operation with selected hospitals in the Netherlands and Germany (Laurentius Hospital Roermond, Atrium Medisch Centrum Heerlen, Máxima Medisch Centrum Veldhoven, Diaconessenhuis Leiden, Helder Kliniek Eindhoven, Coloproktologisches Zentrum Düsseldorf). All consecutive patients visiting the outpatient clinic with complaints of haemorrhoidal disease 2nd to 4th grade (after 2 treatments of Barron ligations) will be considered for the study. All patients have had proctoscopy to determine the grade of haemorrhoidal disease. Furthermore, all patients of over 40 years old have had colonoscopy. Goligher Classification will be used to define the grade of haemorrhoidal disease.

If all inclusion criteria are met and no exclusion criteria are present, a member of the Research Team will inform the patient about the purpose of the study and review all required baseline study data of that patient candidate. After informed consent the patient will be randomly assigned for one of the two study groups: selective haemorrhoidopexy or stapled haemorrhoidopexy. Randomization, data collection and data analysis will be supported by MEMIC (Center for Data and Information Management).

The primary endpoint of the study is two years symptom free period based on Goligher Classification. Secondary endpoints will be recorded and compared between the two groups. The total follow-up will be two years.

It is anticipated that the total length of time required to complete the study will be three and a half years, bases upon the following assumptions:
- 18 months to complete patient enrolments
- 2 years to complete patient follow-up.

Intervention

open selective haemorrhoidopexy versus circular stapled haemorrhoidopexy

Study burden and risks

The risks associated with participation in this trial can be considered equal to standard treatment of haemorrhoidal disease. Experience with complications and adequate logistics are present in every clinic participating in the study. Patients will be informed about these complications before starting treatment.

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

Age above 18 years;Symptoms of haemorrhoidal disease 2nd to 4th grade. In case of 2nd grade haemorrhoidal disease, at least two attempts of Barron ligation must have preceded;Primary or recurrent haemorrhoidal disease;Written informed consent

Exclusion criteria

Acute presentation (not elective)
Concurrent untreated or recurrent colorectal cancer
Concomitant anorectal diseases (fistula, abscess, fissure, polyps)
Prior endoscopic or surgical treatment of haemorrhoids within the past 6 months
Active inflammatory bowel disease
Previous major anorectal surgery
A history of faecal incontinence
Presence of severe rectal pain

ASA >3
The patient is uncooperative or is not capable to return for routine outpatient follow-up
On Coumarine derivate anticoagulation or history of coagulopathy
On immunosuppressant medication
Pregnancy
Non-consenting patients
Unwilling for randomisation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	186
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-03-2013
Application type:	First submission
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
CCMO	NL41309.068.12