HEMARTY
Hemorrhoid Artery Minimalisation A Randomized Trial of a ligation Therapy (Doppler guided HAL versus non-doppler guided HAL procedure)

Published: 29-01-2008
Last updated: 15-05-2024

To determine the cost effectiveness of Doppler located arterial ligation and the random plexus ligation procedure in comparing the long term effectiveness of haemorrhoid treatment with regard to disappearance of clinical symptoms.

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

Summary

ID

NL-OMON30975

Source
ToetsingOnline

Brief title
HEMARTY

Condition

- Anal and rectal conditions NEC

Synonym
piles

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: doppler, hemorrhoid, ligation

Outcome measures

Primary outcome

Cost effectiveness analyses of the artery ligations procedures.

Secondary outcome

To establish the reduction of anal blood flow (decrease of vessel diameter) in

both groups as measured with intra anal Duplex before and after the procedure.

Next to the changes in rectal compliance in both groups as measured with anal

manometry before and after the procedure.

Other secondary parameter/endpoints involve the next items

• The duration of the procedure

• Post operative complications (VAS score)

• Post operative pain

Study description

Background summary

Since 1995 the hemorrhoidal artery ligation (HAL) has been used for submucosal ligation of hemorrhoidal arteries by means of an ultrasonographic transducer (Morinaga et al. 1995). Because of the variations in the local anatomy (Aigner et al. 2004, 2006) and the presence of a circumferential plexus it is to believe that precise localisation of a pulsing bloodstream with doppler is not possible and not necessary. A random ligation (without the specific Doppler tool) in the plexus hemorrhoidalis should therefore result in comparable long

term results as in the procedure with the Doppler tool and could be more cost saving.

Study objective

To determine the cost effectiveness of Doppler located arterial ligation and the random plexus ligation procedure in comparing the long term effectiveness of haemorrhoid treatment with regard to disappearance of clinical symptoms.

Study design

Prospective single blinded randomized clinical trial

Intervention

First group is treated with the HAL procedure with doppler. The second group is treated with the HAL procedure without doppler.

Study burden and risks

Before surgery the subjects are submitted for an ultrasound of the anorectum and for a rectal manometry. After the surgery the subject has to keep up a VAS-score for one week. Six weeks after surgery the subjects are again submitted for an ultrasound and manometry.

Regular follow-up is scheduled at 6 weeks after surgery and subsequently 6, 12 and 24 months after surgery. Each follow-up session includes a rectal examination and a questionnaire (adapted RAND-36) which have to be filled in. Resulting in a total of 4 visits post operatively to the clinic. The ultrasound and manometry of the rectum brings along a certain degree of physical discomfort. There are no specific physiological discomforts associated with participation.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
3430 EM Nieuwegein
Nederland
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
3430 EM Nieuwegein
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age above 18 years
Complains for more than 3 months of haemorrhoid related complains
Haemorrhoid Grade 2 resistant to rubber band ligation
Haemorrhoid Grade 3
ASA 1 and 2

Exclusion criteria

Previous gastro-intestinal malignancy
Previous surgery in the rectum including treatment for haemorrhoids within the last 10 years.
Simultaneously presence of other anal disorders, such as anal fissure, fistula, abscess, colon/anus carcinoma
Unable to understand instructions (eg. Language barrier)

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:	Recruitment stopped
Start date (anticipated):	25-02-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	29-01-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 23917
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL17145.100.07
OMON	NL-OMON23917