Hemorroïd Arterie Minimalisatie: een gerandomiseerd onderzoek van een ligatie therapie.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23917

Source
Nationaal Trial Register

Brief title
HEMARTY

Health condition

Hemorrhoids - hemorroïden
Piles - aambeien

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis
Koekoekslaan 1
3430 EM Nieuwegein
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Cost effectiveness analyses of the artery ligations procedures.

Secondary outcome

1. 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;

2. Next to the changes in rectal compliance in both groups as measured with anal manometry before and after the procedure;

3. The duration of the procedure;

4. Post operative complications (VAS score);

5. 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

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 design

1. Preoperative screening;

2. 6 weeks after intervention;

3. 6 months after intervention.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

1. Age above 18 years;

2. Complains for more than 3 months of haemorrhoid related complains;

3. Haemorrhoid Grade 2, resistant to rubber band ligation;

4. Haemorrhoid Grade 3;

5. ASA 1 and 2 .

Exclusion criteria

1. Previous gastro-intestinal malignancy;

2. Simultaneously presence of other anal disorders, such as anal fissure, fistula, abscess, colon/anus carcinoma;

3. 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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-12-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 30975
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2022
NTR-old	NTR2139
CCMO	NL17145.100.07
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON30975

Study results

Summary results
N/A