Prospectief gerandomiseerd multicenter vergelijkend onderzoek tussen het gebruik van rubberband ligatie en arterie ligatie van de hemorroïdaal arteriën voor de behandeling van graad II en III hemorroïden.

No registrations found.

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

Summary

ID

NL-OMON27930

Source
NTR

Brief title
HEMO

Health condition

Hemorrhoids, piles, THD, HAL, rubberband ligation.

Hemorroïden, aambeien, THD, HAL, Rubberband ligatie

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis, Nieuwegein, Netherlands
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Primairy endpoint is defined as a succesful treatment out of patient perpective. A treatment is considered succesful if the number one complaints has subsided.

Secondary outcome

Secundairy endpoints are:

1. Cost effectivity;

2. Number of treatments neccesary;

3. Number of clinical visits;

4. Number of days not able to work;

5. Number of days of hospitalisation;

6. Postoperative pain;

7. Amount of painmedication used post operative;

8. Post operative complication in the first week after the procedure and during 6 months of follow-up;

9. Number of re-interventions.

Study description

Background summary

In daily practice there are many treatment modalities for hemorrhoids available. Since many years the rubberband ligation is widly used. Recently there are also positive results reported of the artery ligation procedure. This research aims to determine best practice in the treatment of grade II and III hemorrhoids.

The aim of this study is to determine which of the two commen treatment modalities of hemorrhoids known as rubberband liagtion and arterie ligation procedure is best fot the

treatment of grade II or III hemorrhoids.

Study objective

In daily practice there are many treatment modalities for hemorrhoids available. Since many years the rubberband ligation is widly used. Recently there are also positive results reported of the artery ligation procedure. This research aims to determine best practice in the treatment of grade II and III hemorrhoids.

Study design

Follow-up at 6 weeks, and 6 months.

Intervention

Patients are either treated with the rubberband ligationprocedure or with the artery ligation procedure.

Contacts

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Eligibility criteria

Inclusion criteria

1. By means of proctoscopy, physical examnination or sigmoidoscopy proved grade II or III hemorrhoids;

2. No other explanation for rectal bloodloss;

3. Age between 18 and 70 years;

4. Patient understands the Dutch language;

5. Patient is able to decide;

6. Informed consent.

Exclusion criteria

1. Grade I or IV hemorrhoids;

2. Asymptomatic hemorrhoids;

3. Other proctologic disorders;

4. Coagulapathy;

5. Use of coumarine derivates;

6. Anal surgery in history.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-11-2009
Application type:	First submission

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
NTR-new	NL1999
NTR-old	NTR2116
Other	CCMO : ABR26912 / NL26912.100.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A