Prospective randomised multicenter study comparing the outcome of rubberband ligation and artery ligation of the hemorrhoidal arteries in the treatment of grade II and III hemorrhoids.

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

Summary

ID

NL-OMON33371

Source
ToetsingOnline

Brief title
HEMO trial

Condition

- Anal and rectal conditions NEC

Synonym
Hemorrhoids, 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: artery ligation, Hemorrhoids, rubberband ligation

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

• cost effectivity

- number of treatments neccesary

- number of clinical visits

- number of days not able to work

- number of days of hospitalisation

• postoperative pain

•Amount of painmedication used post operative

•Post operative complication in the first week after the procedure and during 6

months of follow-up

•Number of re-interventions

Study description

Background summary

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

Prospective randomised multicenter study

Intervention

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

Study burden and risks

Both procedures are standard procedures. There are no additional risks in participation in this study.

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

- By means of proctoscopy, physical examnination or sigmoidoscopy proved grade II or III hemorrhoids
- No other explanation for rectal bloodloss
- age between 18 and 70 years
- Patient understands the Dutch language
- Patient is able to decide
- informed consent

Exclusion criteria

- grade I or IV hemorrhoids
- asymptomatic hemorrhoids
- other proctologic disorders
- coagulapathy
- use of coumarine derivates
- anal surgery in history

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2010
Enrollment:	200
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	29-10-2009
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

No registrations found.

In other registers

Register	ID
CCMO	NL26912.100.09