

Haemorrhoidal Artery Ligation Study: the surplus value of the Doppler

Published: 24-05-2007

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The objective is that 6 standard ligation of hemorrhoidal arteries is as effective as doppler guided.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal vascular conditions
Study type	Interventional

Summary

ID

NL-OMON30853

Source

ToetsingOnline

Brief title

HAL study

Condition

- Gastrointestinal vascular conditions
- Vascular therapeutic procedures

Synonym

Haemorrhoids

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Artery, Doppler, Haemorrhoid, Ligation

Outcome measures

Primary outcome

No more symptoms (blood loss, pain, pruritis, prolaps) at six months postoperatively

Secondary outcome

Incidence of hamorrhages and bladder retentions first 48 hours

Incidence of other repair related complications

VAS pain score day 1-7

VAS overall satisfaction month 1 + 6

Wexner Fecal Incontinence Score month 1+6

Costs

Maybe same questionairre one year postoperatively

Study description

Background summary

Hemorrhoids is a frequent encountered disease. Symptoms like blood loss, pruritis ani, pain and prolaps are incapacitative for the patient. If conservative treatment fails (like diet), an intervention is indicated. First choice treatment is the rubber-band-ligation. Minimally invasive the base of the hemorrhoids is ligated resulting in less hemorrhoidal tissue. Second choice is more painful, the hemorrhoidectomy. There is however an alternative: doppler guided ligation of the hemorrhoidal artery. Excellent results including less postoperative pain have been reported. In that literature and our own experience showed standard 6 loactions of the hemorrhoid arteries. And sometimes no diminished blood flow is heard with the doppler, although experts

underline this still can be an adequate ligation. Without doppler guidance, 6 standard ligations (at 1,3,5,7,9 and 11 o'clock) could as effective. Additional advantage would be that the special doppler-proctoscope is not necessary anymore. In our institute with approximately 150 patients annually, it would mean a reduction of 45,000 euro in costs.

Study objective

The objective is that 6 standard ligation of hemorrhoidal arteries is as effective as doppler guided.

Study design

A randomized study

Intervention

A ligation of hemorrhoidal arteries doppler guided or at six standard localisations.

Study burden and risks

Burden: completing questionnaires, approximately 20 min in total
Risk: a possible lower success for complete relief of the symptoms

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

Hemorrhoidal disease

Grade II or III

Symptomatic following two rubber-band-ligation-procedures

Written informed consent

Exclusion criteria

Previous ano-rectal surgery

Known coagulation disorder

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):	01-08-2007
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO	
Date:	24-05-2007
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	NL17426.060.07