

# Haemorrhoidal Artery Ligation Study: the surplus value of the Doppler

Published: 24-05-2007

Last updated: 08-05-2024

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal vascular conditions
<b>Study type</b>	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**

### **Public**

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### **Scientific**

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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