

Treatment of Hemorrhoids: Rubber band ligation Or Sclerotherapy

Published: 29-09-2020

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We want to compare the effectiveness of sclerotherapy and rubberband ligation when it comes to symptoms. We will secondarily consider patient satisfaction, complications and recurrences. We hypothesize that both treatments are equally effective.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON52967

Source

ToetsingOnline

Brief title

THROS trial

Condition

- Gastrointestinal therapeutic procedures

Synonym

hemorrhoids, piles

Research involving

Human

Sponsors and support

Primary sponsor: Flevoziekenhuis

Source(s) of monetary or material Support: Flevoziekenhuis

Intervention

Keyword: hemorrhoids, rubber band ligation, sclerotherapy

Outcome measures

Primary outcome

symptoms (ESCP core outcomes): pain, bloodloss, itchiness, prolapse

Secondary outcome

satisfaction, treatment numbers, cross-over, work-leave

Study description

Background summary

Hemorrhoids are a frequent problem in society; it is a problem that can be treated with rubberband ligation or sclerotherapy. Until now there has not been a randomised controlled trial which looks at effectiveness and patient satisfaction of these treatments.

Study objective

We want to compare the effectiveness of sclerotherapy and rubberband ligation when it comes to symptoms. We will secondarily consider patient satisfaction, complications and recurrences. We hypothesize that both treatments are equally effective.

Study design

randomised controlled trial, multicenter

Intervention

Intervention: Sclerotherapy - 2 injections aethoxysklerol 3% (polidocanol)

(Control: Rubberband ligation, 3 rubberbands per session)

Study burden and risks

3 moments to fill in questionnaires; roughly 10-20min per session.

The rest of the treatment is the usual protocol

Contacts

Public

Flevoziekenhuis

Hospitaalweg 1
Almere 1315RA
NL

Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

grade 1 or 2 hemorrhoids, >18 years old

Exclusion criteria

grade 3-4 hemorrhoids, treatment for hemorrhoids in the last year

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-11-2020
Enrollment:	660
Type:	Actual

Ethics review

Approved WMO	
Date:	29-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	27-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL73111.018.20
Other	NL8377