ISRCTN58162568 https://doi.org/10.1186/ISRCTN58162568

The surplus value of doppler in haemorrhoid artery ligation procedure

Submission date	Recruitment status	[ ] Prospectively registered
23/08/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/08/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/08/2007	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S. Nienhuijs

Contact details
Canisius-Wilhelmina Hospital
P.O. Box 9015
Nijmegen
Netherlands
6500 GS
+31 (0)24 365 7657
s.nienhuijs@hccnet.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Standard localised ligations are as feasible as doppler-guided ligations of haemorrhoid arteries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee (Medisch-Ethische toetsingscommissie) on the 24th of May 2007 (ref: METC number M071729).

Study design
Randomised, double-blind, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Haemorrhoid arteries

Interventions
Doppler-guided and standard localised haemorrhoidal artery ligation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Incontinence at four months postoperatively.

Secondary outcome measures
1. Operative variables
2. Visual Analogue Scale (VAS)-pain scores, analgesics (seven days, month one and four)

3. Cleveland Incontinence Score, Complaints (month one and four)
4. Costs

Overall study start date
01/08/2007

Completion date
01/12/2008

Eligibility

Key inclusion criteria
1. Aged greater than 18 years
2. Symptomatic grade II/III/IV haemorrhoids
3. At least one unsuccessful rubber band ligation
4. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
92

Key exclusion criteria
1. Previous anal surgery
2. Bleeding disorder

Date of first enrolment
01/08/2007

Date of final enrolment
01/12/2008

Locations

Countries of recruitment
Netherlands

Study participating centre

Canisius-Wilhelmina Hospital
Nijmegen
Netherlands
6500 GS

Sponsor information

Organisation
Catharina Hospital Eindhoven (The Netherlands)

Sponsor details
Department of Surgery
P.O. Box 1350
Eindhoven
Netherlands
5602 ZA

Sponsor type
Hospital/treatment centre

Website
http://www.catharina-ziekenhuis.nl/

ROR
https://ror.org/01qavk531

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Catharina Hospital Eindhoven (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration