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

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Contact details

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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 summaryNot provided at time of registration