ISRCTN68315343 https://doi.org/10.1186/ISRCTN68315343

An open prospective multicentre randomised study of haemorrhoid excision (Milligan-Morgan) and stapled anopexy (Longo) for the treatment of prolapsing haemorrhoids

Submission date
18/11/2007

Recruitment status
No longer recruiting

Registration date
21/02/2008

Overall study status
Completed

Last Edited
08/08/2011

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
STOPP (Stapled or Open Pile Procedure) trial

Study objectives
To prove that stapled anopexy produces better or at least similar clinical outcome compared to the Milligan-Morgan operation. The outcomes assessed are:
1. Self-reported symptom reduction (submitted by the patients)
2. Anatomical normalisation (submitted by the surgeons)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained for each participating Hospital. Main approval was granted by the Ethics Committee of Linkoping University (Sweden) on the 8th October 1999 (ref: 99099).

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Half of the participants were randomised to the intervention group and another half to the control group.

Intervention group: Stapled anopexy
Control group: Conventional diathermy haemorrhoidecomy

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Self-reported symptom reduction, assessed by a symptom questionnaire filled by the patients pre-treatment and at one year after surgery
2. Anatomical normalisation - a standard assessment of the anatomy by the surgeons before and at one year after surgery

There was also a follow-up visit at 3 - 4 months after surgery, at which the symptom questionnaire and anatomical assessment were carried out. However, the results of these assessments were not included in the final trial outcome; they served the purpose of assessing adverse events and complications.

Secondary outcome measures
1. Operation time
2. Theatre time
3. Complexity of each operation, rated by the surgeon
4. Hospital stay
5. Postoperative pain score. Patients were provided with a diary with instructions to score their pain (0 - 10 visual analogue scale) for each of the first 14 days, beginning from day 1 after surgery. The diary also reported on recovery and use of pain medication.
6. Sick leave
7. Complications, assessed at 3 - 4 month visit to surgeon
8. Adverse events or course, assessed at 3 - 4 month visit to surgeon

Overall study start date
01/05/1999

Completion date
31/12/2001

Eligibility

Key inclusion criteria
1. Haemorrhoid grade III or IV
2. Prolapse of one or more haemorrhoids on examination, together with parts of the anal canal, or a prolapse that can be provoked by digital traction on the (reduced) haemorrhoid

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Retained anal canal
2. No consistent history of haemorrhoid prolapse
3. A history of severe anal fistula (high fistula) or a ruptured anal sphincter (obstetric injury) will usually disqualify the patient from participation in this trial

Date of first enrolment
01/05/1999

Date of final enrolment
31/12/2001

Locations

Countries of recruitment
Denmark

Sweden

United Kingdom

Study participating centre
Karolinska Institute
Stockholm
Sweden
14186

Sponsor information

Organisation
Ethicon Endo-Surgery (Germany)

Sponsor details
Ethicon Endo-Surgery (Europe) GmbH
Hummelsbuttler Steindamm 71
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Sponsor type
Industry

ROR
https://ror.org/023edjq13

Funder(s)

Funder type
Industry

Funder Name
Ethicon Endo-Surgery Europe (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2010		Yes	No