

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/08/2011	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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 Linköping University (Sweden) on the 8th October 1999 (ref: 99099).

Study design

Multi-centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

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 haemorrhoidectomy

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

United Kingdom

Denmark

Sweden

Study participating centre

Karolinska Institute

Stockholm

Sweden

14186

Sponsor information

Organisation

Ethicon Endo-Surgery (Germany)

ROR

<https://ror.org/023edjq13>

Funder(s)

Funder type

Industry

Funder Name

Ethicon Endo-Surgery Europe (Germany)

Results and Publications

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