

Randomised trial of stapled anopexy in local perianal block or general anaesthesia

Submission date 03/09/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/10/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/10/2008	Condition category Digestive System	☐ 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

Study information

Scientific Title

Study objectives

Stapled anopexy under perianal local block is as effective as surgery under general anaesthesia and provides a similar clinical outcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Committee of Research and Ethics, University Hospital, Linköping (Sweden) on the 11th March 2003 (ref: 03-087).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mucoanal prolapse

Interventions

Perianal local anaesthetic block versus general anaesthesia for stapled anopexy.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Symptom resolution after the operation was measured by five symptom questions (bleeding, pruritus, soiling, pain and prolapse) and graded by their frequency. The five symptoms were assessed at pre-operative examination and post-operative reexamination which was scheduled approximately 3 - 6 months after the procedure
2. Restoration of anatomy in the anal canal was measured by a post-operative examination 3 - 6 months after the operation

Key secondary outcome(s)

1. Surgeon's ratings of severity of the disease, complexity of the operation and success of the operation were measured with a 7-point scale. They were registered with protocol during the pre-operative examination, during the operation and during post-operative examination 3 - 6 months post-operatively
2. Post-operative pain, post-operative course and complications were measured by a patient diary and at examination
3. Operation time and staple line height were registered during the operation

Completion date

30/11/2005

Eligibility**Key inclusion criteria**

1. Patients with mucoanal prolapse that needed manual reposition of the prolapse or had confirmed prolapse at examination

2. No age restriction
3. Patients had to be considered suitable for either general anaesthesia or a local anaesthetic block

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Patients who were considered unsuitable for a general anaesthetic in the context of a minor anal prolapse
2. Patients with other condition than mucoanal prolapse

Date of first enrolment

01/04/2004

Date of final enrolment

30/11/2005

Locations

Countries of recruitment

Sweden

Study participating centre**Department of Surgery**

Linköping

Sweden

SE- 581 85

Sponsor information

Organisation

County Council of Ostergotland (Sweden)

ROR

<https://ror.org/0326gsy75>

Funder(s)

Funder type

Government

Funder Name

County Council of Ostergotland (Sweden) (ref: 060-48559)

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	01/11/2008		Yes	No