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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/10/2007	**Overall study status** Completed	
Last Edited 30/10/2008	**Condition category** Digestive System	

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

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, Linkoping (Sweden) on the 11th March 2003 (ref: 03-087).

Study design
Ramdomised 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
Mucoanal prolapse

Interventions
Perianal local anaestetic block versus general anaesthesia for stapled anopexy.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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

Secondary outcome measures
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 dairy and at examination
3. Operation time and staple line height were registered during the operation

Overall study start date
01/04/2004

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

Age group
Other

Sex
Both

Target number of participants
50

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
Linkoping
Sweden
SE- 581 85

Sponsor information

Organisation
County Council of Ostergotland (Sweden)

Sponsor details
University Hospital
Linkoping
Sweden
SE-581 85

Sponsor type
Government

Website
http://www.lio.se/templates/Page.aspx?id=4033

ROR
https://ror.org/0326gsy75

Funder(s)

Funder type
Government

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

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	01/11/2008		Yes	No