

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

<b>Submission date</b> 03/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/10/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/10/2008	<b>Condition category</b> Digestive 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**  
Dr Roger Gerjy

**Contact details**  
Department of Surgery  
University Hospital  
Linköping  
Sweden  
SE- 581 85

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

**Study design**

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**

Mucoanal prolapse

**Interventions**

Perianal local anaesthetic 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 diary 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**  
Linköping  
Sweden  
SE- 581 85

## Sponsor information

**Organisation**  
County Council of Ostergotland (Sweden)

**Sponsor details**  
University Hospital  
Linköping  
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?
<a href="#">Results article</a>	Results	01/11/2008		Yes	No