

# Randomised controlled trial: groin hernia repair with titanium coated mesh compared to prolene mesh

<b>Submission date</b> 13/11/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/09/2008	<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

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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**

Lightweight titanium-coated mesh gives a faster time of convalescence and return to work and normal activity compared to standard heavyweight mesh prolene.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the Ethics Committee of (Forskningsetikommitten) University Hospital on the 3rd December 2005 (ref: 03-428).

### **Study design**

Randomised controlled clinical 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**

Primary unilateral inguinal hernia in men

### **Interventions**

A tension free repair using the Lichtenstein technique is performed, with local anaesthetics administered into the wound peroperatively. The basic principle is one unit, one surgeon, one method, and two meshes (randomised):

1. Lightweight titanium-coated mesh
2. Heavyweight prolene mesh

All operations are done in the same outpatient clinic under general anaesthesia. The surgeon is highly specialised, performing more than 500 hernia repairs a year and has over 30 years of operative experience.

### **Intervention Type**

Other

### **Phase**

Not Specified

**Primary outcome measure**

Short-term convalescence, is evaluated by using a validated questionnaire in form of a diary assessing postoperative symptoms and recovery at rest and some other activities, which the patients after completion return by mail. It includes Visual Analogue Scales (VAS) ranging from 0 (no pain) to 100 mm (worst imaginable pain) to estimate preoperative pain, and experienced pain on day 1, 2, 3, 4, and 8 weeks after the operation. It also includes questions about time to return to work and normal activity.

**Secondary outcome measures**

One-year follow-up results:

1. Testicular atrophy, recurrence and chronic pain and discomfort (VAS) are assessed at the clinical visit
2. Quality of life is assessed using the Short Health Scale (SHS), regarding the intensity of symptoms, how much worries they cause and how they affect daily life and general well-being

**Overall study start date**

01/02/2004

**Completion date**

30/06/2006

**Eligibility****Key inclusion criteria**

Men in the age from 20 to 75 years with an elective Lichtenstein repair of a unilateral primary inguinal hernia were eligible to participate in the study. The patients were recruited and had their surgery in a clinic specialised in elective out-patient operations.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Male

**Target number of participants**

300

**Key exclusion criteria**

Patients who were unable to walk 500 metres or unlikely to participate in the follow up (for example owing to language difficulties) were excluded.

**Date of first enrolment**

01/02/2004

**Date of final enrolment**

30/06/2006

# Locations

## Countries of recruitment

Sweden

## Study participating centre

Djurgardsg 58

Linköping

Sweden

582 29

# Sponsor information

## Organisation

State Health Care in Ostergotland County (Landstingen i Ostergotland) (Sweden)

## Sponsor details

S:t Larsg 49 B

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landstinget@lio.se

## Sponsor type

Government

## Website

<http://www.lio.se>

# Funder(s)

## Funder type

Government

## Funder Name

State Health Care in Ostergotland County (Landstingen i Ostergotland) (Sweden)

# 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	01/10/2008		Yes	No