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

Submission date	Recruitment status	[_] Prospectively registered
13/11/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/01/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/09/2008	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 (Forskningsetikkommitten) University Hospital on the 3rd December 2005 (ref: 03-428).

Study design
Randomised controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
Linkoping
Sweden
582 29

Sponsor information

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

Funder(s)

Funder type
Government

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

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	01/10/2008		Yes	No