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Randomised controlled trial to compare all aspects of laparoscopic hernia repair with conventional open technique

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 06/12/2019	**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
REC00024

Study information

Scientific Title
Randomised controlled trial to compare all aspects of laparoscopic hernia repair with conventional open technique

Study objectives
The aim of the proposed study is to compare, in a prospective RCT, the extra-peritoneal laparoscopic hernia repair with the open 'Lichtenstein' repair.
Primary assessments and comparisons will be made concerning:
1. Incidence of pre- and post-operative complications
2. Time to return to normal activities/work/sport
Secondary assessments and comparisons will be made concerning:
1. Severity and duration of post-operative pain
2. Duration of operation
3. Overall patient satisfaction
4. Cost effectiveness
In addition, the feasibility of increasing the proportion of patients with inguinal hernia who can be operated on as day cases will be evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Digestive system diseases

Interventions
Extra-peritoneal laparoscopic hernia repair vs open 'Lichtenstein' repair.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Post-operative complications: patients will be seen 1 and 2 weeks after surgery and then yearly thereafter. Wounds will be reviewed by an independent observer on each occasion the patients are seen. Classification will be into two groups: 1 = Clean, 2 = Infection with sero-sanguinous or purulent discharge. Suture line erythema will be ignored. Microbiological swabs of any abnormal discharge will be taken for culture. Other complications specific to hernia repairs will also be assessed by an independent observer and will be recorded on standard forms. The independent observer will be the research nurse, or any doctor who is assisting in the out-patient clinic (other than one of the investigators). All patients will be kept under review for at least 3 years.

Time to return to normal activities/work: to avoid the potential problems of a discrepancy between patients' ability to return to work and their motivation, they will be asked to perform a series of straight leg raises in the clinic pre-operatively and at 1 and 2 weeks post-operatively. The tests will involve lifting and returning the leg on the appropriate side to an angle of 45 degrees, with the knee straight, in time to a metronome set at a specified rate. They will be asked to stop when they can no longer keep up with the metronome. This test has been previously validated and will be administered by the research nurse. At each outpatient visit, patients will be assessed as to whether or not their hernia repair limits their daily activities by answering a series of questions related to various common activities of daily living. Working patients will be asked how many days off work were taken post surgery. More specifically, assessments will be made as to whether they could have returned earlier and the reasons for not doing so. Patients not working will be asked how many days after the operation they were able to return to normal activities including sport.

Secondary outcome measures
Post-operative pain: post-operative pain relief will be standardised. Patients will be asked to return any unused tablets with them when they return for their first out-patient visit; the number of returned tablets will be recorded. Patients will also be asked if they have taken any pain relief other than that provided.

Duration of operation: all operative details will be recorded on standard forms. Duration of operation represents the time from first incision to insertion of last stitch.

Cost effectiveness: equipment used, whether days off work (either patient or partner) resulted in personal financial loss and cost to the community in days lost will be measured. More detailed costing studies will be carried out for a sample group.

Patient satisfaction: patients will be required at every post-operative visit to rate their overall satisfaction with the operation.

Overall study start date
01/04/1995

Completion date
01/08/1999

Eligibility

Key inclusion criteria
Patients over the age of 20 years who have a simple inguinal hernia, bilateral inguinal hernia or a recurrent hernia. The patients will be counselled in detail regarding all aspects of both laparoscopic and Lichtenstein repair.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Irreducible, partly reducible or strangulated hernia
2. Previous major lower abdominal incisions (appendicectomy acceptable)
3. Unfit for a general anesthetic
4. Giant scrotal hernia
5. Pregnancy

Date of first enrolment
01/04/1995

Date of final enrolment
01/08/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's Healthcare NHS Trust
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

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Funder(s)

Funder type
Government

Funder Name
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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