

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
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 06/12/2019	Condition category Digestive System	☐ Individual participant data
		☐ Record updated in last year

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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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**

United Kingdom

England

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)

Funder(s)**Funder type**

Government

Funder Name

NHS Executive London (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration