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Randomised controlled trial of laparoscopic versus open repair of inguinal hernia

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/04/2009	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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
Added as of 22/05/2008:
To establish the safety, short term outcome, and theatre costs of transabdominal laparoscopic repair of inguinal hernia performed as day surgery.

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

Health condition(s) or problem(s) studied
Inguinal hernia

Interventions
Laparoscopic or open repair of inguinal hernia

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Added 16/04/2009:
1. Morbidity
2. Post-operative pain and use of analgesics
3. Quality of life
4. Theatre costs

Outcome was assessed by questionnaires administered to patients daily for 10 days and at six weeks post-operatively and by outpatient review at six weeks.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/1992

Completion date
30/06/1994

Eligibility

Key inclusion criteria
1. Primary, unilateral inguinal hernia
2. Aged less than 70 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
125

Key exclusion criteria
Previous major abdominal surgery

Date of first enrolment
01/12/1992

Date of final enrolment
30/06/1994

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Milton Keynes General Hospital Trust
Milton Keynes
United Kingdom
M6 5AZ

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (UK)

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?
Results article	Results	14/10/1995		Yes	No