

# Randomised controlled trial of laparoscopic versus open repair of inguinal hernia

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/04/2009	<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

**Contact name**  
Mr Douglas McWhinnie

**Contact details**  
Milton Keynes General Hospital Trust  
Milton Keynes  
United Kingdom  
M6 5AZ

## 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?
<a href="#">Results article</a>	Results	14/10/1995		Yes	No