A prospective randomised trial of magnetic resonance imaging versus endoscopic retrograde cholangiopancreatography evaluation of patients with suspected cholelithiasis

Submission date 12/09/2003	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 12/09/2003	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 22/04/2008	Condition category Digestive System	Individual participant data

Plain English summary of protocol Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Mr IJ Beckingham

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0192090461

Study information

Scientific Title

Study objectives

To determine the diagnostic accuracy of magnetic resonance cholangiopancreatography versus endoscopic cholangiopancreatography (ERCP) detection of choledocholithiasis in patients undergoing laparoscopic cholecystectomy.

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) Screening

Participant information sheet

Health condition(s) or problem(s) studied Cholelithiasis

Interventions

Patients were randomised to: 1. Endoscopic retrograde cholangiopancreatography 2. Magnetic resonance cholangiopancreatography

Intervention Type

Other

Phase Not Specified

Primary outcome measure

Laparoscopic cholecystectomy and on table cholangiogram to confirm that the common bile duct is clear of stones.

Secondary outcome measures Not provided at time of registration

Overall study start date 27/07/2001

Completion date 01/01/2004

Eligibility

Key inclusion criteria Total number of subjects = 168.

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 168

Key exclusion criteria Not provided at time of registration

Date of first enrolment 27/07/2001

Date of final enrolment 01/01/2004

Locations

Countries of recruitment England

United Kingdom

Study participating centre

Department of Surgery Nottingham United Kingdom NG7 2UH

Sponsor information

Organisation Department of Health (UK)

Sponsor details Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type Government

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

Funder(s)

Funder type Government

Funder Name Queens Medical Centre University Hospital NHS Trust (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?
<u>Results article</u>	Results	01/07/2003		Yes	No