Early laparoscopic cholecystectomy versus conventional management for newly diagnosed gallbladder disease

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
08/09/2009	Digestive System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N0192151057

Study information

Scientific Title

A randomised controlled trial of early laparoscopic cholecystectomy versus conventional management for newly diagnosed gallbladder disease: a cost minimisation and outcome study

Study objectives

Comparing the direct hospital-based and the societal costs of early and conventional management for newly diagnosed gallbladder disease.

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gallbladder diseases

Interventions

- 1. Laparoscopic cholecystectomy
- 2. Analgesia intravenous fluids and antibiotics

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

To see whether early management has a bearing on gallstone related morbidity and mortality.

Key secondary outcome(s))

Not provided at time of registration

Completion date

28/02/2007

Eligibility

Key inclusion criteria

- 1. Male and females
- 2. Aged 18 80 years
- 3. Residing in Nottingham area
- 4. Presenting with primary diagnosis of bilary colic or acute cholecystitis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Patients diagnosed with acute severe gallstone pancreatis or gallstone-related ascending cholangitis (Jaundice temperature greater than 39°C and rigors)
- 2. Patients less than 18 or more than 80 years
- 3. Patients who have medical co-morbidity preventing either laparoscopic cholecystectomy or potential inclusion in either treatment arm

Date of first enrolment

01/09/2004

Date of final enrolment

28/02/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Division of GI Surgery

Nottingham United Kingdom NG7 2UH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Queens Medical Centre University Hospital (UK) - NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created I	Date added	Peer reviewed?	Patient-facing?
Results article	cost utility results	01/09/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes