

Early laparoscopic cholecystectomy versus conventional management for newly diagnosed gallbladder disease

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/09/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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
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 biliary 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 pancreatitis 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	Date added	Peer reviewed?	Patient-facing?
Results article	cost utility results	01/09/2009		Yes	No