

# Early laparoscopic cholecystectomy versus conventional management for newly diagnosed gallbladder disease

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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/09/2004

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

138 (69 each in the early and conventional groups)

**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**

England

United Kingdom

**Study participating centre**

**Division of GI Surgery**

Nottingham

United Kingdom

NG7 2UH

## **Sponsor information**

**Organisation**

Department of Health

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

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

## **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>	cost utility results	01/09/2009		Yes	No