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The timings of cholecystectomy in acute pancreatitis

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 22/04/2015	**Condition category** Digestive System	

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
N0072101043

Study information

Scientific Title

The timings of cholecystectomy in acute pancreatitis: a randomised controlled trial

Study objectives
1. Does a cholecystectomy within 2 weeks of an attack of acute pancreatitis prevent recurrent pancreatitis events?
2. Does a cholecystectomy within 2 weeks compared with delayed surgery (6 weeks) affect complications and hospital stay duration?

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
Pancreatitis

Interventions
Patients with acute gallstone pancreatitis will be randomised to undergo early (2 weeks) or late (6 weeks) cholecystectomy.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Risk of recurrent pancreatitis in delayed surgery groups
2. Operative complication rate
3. Local complications in delayed surgery group such as pseudocyst
4. Total length of time in hospital - mortality rates

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2001

Completion date
01/04/2003

Eligibility

Key inclusion criteria
All patients admitted with acute pancreatitis secondary to gallstones will be admitted into study.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Approximately 100 participants

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2001

Date of final enrolment
01/04/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Countess of Chester NHS Trust
Chester
United Kingdom
CH3 1UL

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
Countess of Chester 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