# The timings of cholecystectomy in acute pancreatitis

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

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

Mr Paul Edwards

#### Contact details

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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