

# Pancreatitis of biliary origin: Optimal timing CHolecystectomy (PONCHO) trial

<b>Submission date</b> 26/05/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/10/2015	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

**Study website**  
<http://www.pancreatitis.nl>

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

Pancreatitis of biliary origin: Optimal timing CHolecystectomy (PONCHO) trial. A randomised controlled multicentre trial of the Dutch Pancreatitis Study Group.

### **Acronym**

PONCHO

### **Study objectives**

Current hypothesis as of 24/04/2012

We hypothesise that early timing of laparoscopic cholecystectomy (ELC) would reduce recurrent biliary pancreatitis or other complications of gall-stone disease in patients with mild biliary pancreatitis.

Study conducted in accordance with the principles of the Declaration of Helsinki and in accordance with the Medical Research Involving Human Subjects Act (WMO).

Previous hypothesis

We hypothesise that early timing of laparoscopic cholecystectomy (ELC) would prevent recurrent biliary pancreatitis or other complications of gall-stone disease in patients with mild biliary pancreatitis.

Study conducted in accordance with the principles of the Declaration of Helsinki.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved by the Arnhem-Nijmegen Regional Committee on Research Involving Human Subjects (Commissie Mensgebonden Onderzoek [CMO] regio Arnhem-Nijmegen).

The study protocol will also be approved by all participating hospitals.

### **Study design**

Multicentre randomised controlled parallel group superiority 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 contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Mild biliary pancreatitis

**Interventions**

1. Intervention group:

Laparoscopic cholecystectomy within 72 hours after randomisation (ELC).

2. Control group:

Laparoscopic cholecystectomy 25-30 days after randomization (ILC).

Patients are randomised when the treating physician feels the patient can be discharged within 1-2 days and all signs of acute disease have resolved.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Current primary outcome as of 24/04/2012

Composite endpoint: Unplanned re-admission for biliary events (recurrent biliary pancreatitis, acute cholecystitis, choledocholithiasis mandating ERCP, biliary colics) and mortality

Previous primary outcome

Composite endpoint: Unplanned re-admission for biliary events (recurrent biliary pancreatitis, acute cholecystitis, choledocholithiasis mandating ERCP, biliary colics)

**Secondary outcome measures**

1. Individual components of the primary endpoint

2. Number of biliary colics after randomisation

3. Length of hospital stay

4. Operation difficulty (VAS)

5. Duration

6. Complications and conversion rate of laparoscopic cholecystectomy

7. Costs per primary endpoint avoided

8. Quality adjusted life year (QALY) gained

9. Mortality

10. Patient satisfaction

**Overall study start date**

01/01/2011

**Completion date**

01/07/2013

# Eligibility

## Key inclusion criteria

Current inclusion criteria as of 24/04/2012

1. Age 18 years or older
2. Mild (non-severe) biliary pancreatitis; no pancreatic necrosis and/or peripancreatic collections and no persistent (>48hr) organ failure
3. First episode of acute pancreatitis
4. Written and oral informed consent (obtained prior to randomisation)

Previous inclusion criteria

1. Age 18 years or older
2. Mild (non-severe) biliary pancreatitis, without sterile pancreatic necrosis and/or peripancreatic collections.
3. Written and oral informed consent (obtained prior to randomisation)

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

266

## Key exclusion criteria

Current exclusion criteria as of 24/04/2012

1. Patients <18 years
2. Patients >75 years with ASA III
3. ASA IV and V patients
4. Patients with ongoing alcohol abuse or chronic pancreatitis
5. Pregnancy

Previous exclusion criteria

1. Patients <18 years
2. Patients >75 years with ASA III
3. ASA IV and V patients
4. Patients with history of alcohol abuse or chronic pancreatitis
5. Mild pancreatitis with sterile pancreatic necrosis and/or peripancreatic collections
6. Severe pancreatitis: persistent (>48hrs) organ failure or necrotizing pancreatitis

## Date of first enrolment

01/01/2011

**Date of final enrolment**

01/07/2013

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Dutch Pancreatitis Study Group**

Nijmegen

Netherlands

6500HB

## **Sponsor information**

**Organisation**

Radboud University Nijmegen Medical Centre (Netherlands)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.pancreatitis.nl>

**ROR**

<https://ror.org/05wg1m734>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Radboud University Nijmegen Medical Centre (Netherlands) - internal 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="#">Protocol article</a>	protocol	26/11/2012		Yes	No
<a href="#">Results article</a>	results	26/09/2015		Yes	No