

Pancreatitis of biliary origin: Optimal timing CHOLEcystectomy (PONCHO) trial

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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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	results	26/09/2015		Yes	No
Protocol article	protocol	26/11/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes