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Pancreatitis of biliary origin: Optimal timiNg CHOlecystectomy (PONCHO) trial

Submission date	Recruitment status	[X] Prospectively registered
26/05/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2015	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.pancreatitis.nl

Contact information

Type(s)
Scientific

Contact name
Prof H G Gooszen

Contact details
Dutch Pancreatitis Study Group
Department of Surgery
Radboud University Nijmegen Medical Centre
HP 690
PO Box 9101
Nijmegen
Netherlands
6500HB
+31 (0)243 655764 / 66458
H.Gooszen@ok.umcn.nl

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
Curent 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
Dutch Pancreatitis Study Group
Department of Surgery
HP 557
PO Box 9101
Mobile: +31 (0)617401029
Nijmegen
Netherlands
6500HB

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?
Protocol article	protocol	26/11/2012		Yes	No
Results article	results	26/09/2015		Yes	No