Pancreatitis of biliary origin, Optimal timiNg of CHOlecystectomy (PONCHO)

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To compare the outcome of early laparoscopic cholecystectomy (

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON36818

Source
ToetsingOnline

Brief title
PONCHO trial

Condition

- Exocrine pancreas conditions
- Bile duct disorders
- Hepatobiliary therapeutic procedures

Synonym
biliary pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - biliary pancreatitis, - cholecystectomy, - cholecystitis, - gallstones

Outcome measures

Primary outcome

Acute re-admission for biliary events (recurrent biliary pancreatitis, acute

cholecystitis,

choledocholithiasis mandating ERCP or biliary colics).

Secondary outcome

- patient satisfaction, medical and indirect costs in terms of volumes of

resource utilization in relation to outcome (cost-effectiveness analysis)

- individual components of the primary endpoint: number of biliary colics after

randomization, length

of stay, difficulty of operation (VAS), duration and complications of

cholecystectomy, conversion rate of laparoscopic to open

cholecystectomy, length of stay, mortality.

Study description

Background summary

After biliary pancreatitis, cholecystectomy should be performed in order to reduce recurrent biliary disease (pancreatitis, cholecystitis). Current guidelines advocate cholecystectomy to be performed within 2-4 weeks after discharge. During that period, however, the patient is at risk for recurrent biliary disease. Based on a pilot study and a systematic review we expect that early laparoscopic cholecystectomy (<72 hrs after randomization), as compared to interval cholecystectomy (25-30 days after randomization), reduces recurrent biliary disease after mild

biliary pancreatitis.

Study objective

To compare the outcome of early laparoscopic cholecystectomy (<72 hrs after randomization) with interval laparoscopic cholecystectomy (25-30 days after randomization) after mild biliary pancreatitis.

Study design

A randomized controlled parallel-group superiority trial in 18 Dutch hospitals.

Intervention

A) Laparoscopic cholecystectomy within 72h after randomization, versus
B) Laparoscopic cholecystectomy 25-30 days after randomization.

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

Study burden and risks

Research has shown that there is probably not a potential risk of an early laparoscopic cholecystectomy compared to an interval laparoscopic cholecystectomy. The burden is minimal, average 1 hour in total (forms, telephone follow-up and questionnaire).
However the minimalisation of recurrent biliary disease due to an early intervention is a clear benefit for patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- age 18 years or older
- mild (non-severe) biliary pancreatitis, without sterile pancreatic necrosis and/or peripancreatic collections.
- first episode of pancreatitis
- written and oral informed consent

Exclusion criteria

- patients <18 years
- patients >75 years with ASA III
- ASA IV and V patients
- patients with history of alcohol abuse or chronic pancreatitis
- mild pancreatitis with sterile pancreatic necrosis and/or peripancreatic collections
- severe pancreatitis: persistent (>48hrs) organ failure or necrotizing pancreatitis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	266
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-05-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL32395.091.10

Study results

Date completed:	18-02-2014
Actual enrolment:	266