

Acute biliary Pancreatitis: early Endoscopic retrograde cholangiography plus sphincterotomy versus Conservative treatment (APEC trial)

Submission date 13/11/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/12/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/07/2020	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Acute biliary pancreatitis is inflammation of the pancreas caused by obstruction of the pancreatic duct. Relieving the obstruction early with an operation called endoscopic retrograde cholangiography (ERC) plus endoscopic sphincterotomy (ES) may be beneficial. The aim of this study is to investigate whether early ERC plus ES reduces complications and/or the number of deaths in patients with acute biliary pancreatitis.

Who can participate?

Patients aged over 18 with acute biliary pancreatitis.

What does the study involve?

Participants are randomly allocated to one of two groups. One group undergoes early ERC plus ES (i.e., within 24 hours of admission to hospital). The other group receives conservative treatment and delayed ERC is performed when clinically indicated.

What are the possible benefits and risks of participating?

Patients in the early ERC/ES group may benefit from early clearance of the obstruction. This procedure may also lead to complications in a minority of patients. Patients in the conservative treatment group may be disadvantaged by reduced biliary drainage. The study design has several safety procedures and evaluation moments to guarantee the patients' safety throughout the study.

Where is the study run from?

25 participating centers in the Netherlands.

When is the study starting and how long is it expected to run for?

March 2013 to April 2016.

Who is funding the study?
Fonds NutsOhra and Erasmus Medical Center, Rotterdam, the Netherlands.

Who is the main contact?
Prof. M.J. Bruno
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Acute biliary Pancreatitis: early Endoscopic retrograde cholangiography plus sphincterotomy versus Conservative treatment (APEC trial): a randomized, superiority, assessor-blinded multicenter trial

Acronym
APEC

Study objectives
We hypothesize that early endoscopic retrograde cholangiography (ERC) plus sphincterotomy improves the outcome of patients with acute biliary pancreatitis without cholangitis in whom the disease course is predicted to be severe.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Erasmus Medical Center Rotterdam Ethics Committee, 08/11/2012 ref: MEC-2012-357

Study design

Randomized superiority assessor-blinded multicenter trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information can be found at <http://www.pancreatitis.nl/>

Health condition(s) or problem(s) studied

Acute biliary pancreatitis

Interventions

The trial will be performed by the Dutch Pancreatitis Study Group. A total of 232 patients will be randomized in 25 participating centers of the Dutch Pancreatitis Study Group.

1. Intervention group: early (<24 hours of admission) ERC plus sphincterotomy.
2. Comparison group: conservative (expectative) management, delayed ERC when clinically indicated.

The total duration of follow-up is until 6 months after randomization.

Intervention Type

Procedure/Surgery

Primary outcome measure

A composite of severe morbidity and mortality occurring until 6 months after randomization.

Severe morbidity is defined as the occurrence of persistent single organ failure, necrotizing pancreatitis, bacteremia, cholangitis, pneumonia or exocrine or endocrine pancreatic insufficiency.

Secondary outcome measures

1. Individual components of the primary endpoint
2. Length of hospital stay

3. Need for of new intensive care admission
4. Length of intensive care stay
5. Respiratory complications
6. ERC related complications
7. Number of endoscopic, radiological and operative (re-)interventions
8. Readmission for biliary events
9. Difficulty of cholecystectomy
10. Economical evaluation

Overall study start date

01/12/2012

Completion date

31/10/2017

Eligibility

Key inclusion criteria

1. Acute biliary pancreatitis
2. Predicted severe disease course
3. ERC with sphincterotomy can be performed within 24 hours after admission
4. Age > 18 years
5. Written informed consent
6. In case of a previous episode of necrotizing pancreatitis, patient should be fully recovered

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

232 patients

Total final enrolment

232

Key exclusion criteria

1. Cholangitis
2. Acute pancreatitis due to other causes such as alcohol abuse, metabolic causes, medication, trauma, etc.
3. Previous (precut) sphincterotomy

4. Chronic pancreatitis
5. INR that cannot be corrected with co-factor or fresh frozen plasma below 1.5
6. Pregnancy

Date of first enrolment

01/03/2013

Date of final enrolment

30/04/2016

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

3015CE

Sponsor information

Organisation

Erasmus Medical Center (Netherlands)

Sponsor details

Dutch Pancreatitis Study Group

Department of Gastroenterology and Hepatology

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Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Charity

Funder Name

Fonds NutsOhra (Netherlands) ref: 1203-052

Alternative Name(s)

NutsOhra Foundation, NutsOhra Fund, Stichting Nuts Ohra

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Funder Name

Pancreas Society (Alvleeskliervereniging) (Netherlands)

Funder Name

Erasmus Medisch Centrum

Alternative Name(s)

Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

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	05/01/2016		Yes	No
Results article	results	18/07/2020	21/07/2020	Yes	No