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

Submission date
13/11/2012

Recruitment status
No longer recruiting

Registration date
17/12/2012

Overall study status
Completed

Last Edited
21/07/2020

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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-fact 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)

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

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	18/07/2020	21/07/2020	Yes	No
Protocol article	protocol	05/01/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes