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How long to wait before operating on the gall bladder after gallstone-induced acute pancreatitis?

Submission date 29/10/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 20/11/2018	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/11/2019	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute pancreatitis is a sudden inflammation of the pancreas (an organ near the stomach that produces substances that aid digestion and regulate blood sugar levels). In most cases, this inflammation is caused by gallstones, in which cases the solution is to remove the gall bladder as soon as possible, where these stones are produced. Without gall bladder removal after recovery from pancreatitis, several complications may occur, including repeated acute pancreatitis, inflammation of the gall bladder, blockage or inflammation of the bile ducts, biliary colic (sudden pain). However, in some cases, removing the gall bladder as soon as possible can be difficult and may lead to complications. A technique called ERCP, which clears the bile ducts, can avoid these complications.
The aim of the EMILY trial is to combine a surgical treatment (removal of gall bladder) and a gastroenterological procedure (ERCP) to investigate if ERCP with delayed surgical treatment (45 to 60 days after discharge) compared with ERCP with early surgical treatment (within 6 days after discharge) could reduce repeated biliary events.

Who can participate?
Adults with mild gallstone-induced pancreatitis

What does the study involve?
Participants will be randomly allocated to one of two groups, group A or group B. Both groups will have their gall bladder removed, as suggested by international practice; however, the timing will differ between the two groups.
Group A is the early group and removal of the gall bladder will be performed 6 days after discharge.
Group B is the delayed group and the removal of the gall bladder will be carried out within 45-60 days after discharge.
Participants will be asked about any gallstone-related events using questionnaires during the follow-up period.

What are the possible benefits and risks of participating?
The benefit of participating is that participants will have the security and confidence that the operation will be performed on time (within 6 days or 45-60 days after discharge). This operation is routinely performed 30 minutes last procedure; however, the waiting lists can last for up to half a year. In this study, there will be no waiting list or delays. Patients will receive attention and follow-up from health care personnel that is sadly not always ensured in regular healthcare.
The possible risk for participants in group A (early removal of gall bladder) is that the procedure may be difficult and there may be complications due to previous inflammation.
For participants in group B (delayed removal of gall bladder), there may be a higher risk for recurrent AP. However, ERCP is performed to lower this risk. If recurrent AP does develop, then participants can return to the hospital for immediate surgery.
The ERCP procedure should prevent any significant differences between groups A and B.

Where is the study run from?
University of Pécs Medical School Institute of Translational Medicine (Hungary)

When is the study starting and how long is it expected to run for?
June 2018 to May 2025 (updated 14/11/2019, previously: May 2020)

Who is funding the study?
University of Pécs Medical School (Hungary)

Who is the main contact?
Professor Péter Hegyi, Head of the Institute of Translational Medicine University of Pécs Medical School
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
V1

Study information

Scientific Title
EMILY: Endoscopic sphincterotoMy for delayIng choLecYstectomy in mild acute biliary pancreatitis

Acronym
EMILY

Study objectives
Cholecystectomy on admission after acute pancreatitis (AP) is difficult sometimes and may be risky to some patients. However, if the operation is delayed, the risk of recurrent AP increases. Gastroenterologists and surgeons have to decide whether to operate on patients upon admission, or to delay the surgery.
We hypothesize that carrying out an ERCP/ES allows us to delay cholecystectomy without increasing the risk for recurrent pancreatitis, thus making it logistically easier to perform and potentially increasing the efficacy and safety of the procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ministry of Human Capacities, Chief Medical Officer of State, 18/04/2018, 11861-9/2018/EÜIG

Study design
Interventional prospective multi-centre randomised controlled trial

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild biliary pancreatitis

Interventions
Participants will be randomised by the study coordinator using a randomisation module with sealed envelope. This randomisation module will allocate the participants to the 2 different groups. Allocation will be carried out based on predefined randomisation lists created separately for each recruiting centre. The allocation sequence will be prepared with a block size of 4 and with an allocation ratio 1:1 by the Independent Data Management Board (IDMB).
This method makes it impossible for researchers to predict the allocation of the patients involved in the study. It is impossible to conceal the distribution of the patients in this study because the patients need to be scheduled for either an early cholecystectomy or a delayed cholecystectomy.
The patients are randomized to 2 groups:
1. Early cholecystectomy (within 6 days after discharge)
2. Delayed (interval) cholecystectomy (45-60 days after discharge)
There will be a follow-up 90 days after discharge

Intervention Type
Procedure/Surgery

Primary outcome(s)
Composite endpoint, which is based on mortality and on the following recurrent biliary events:
1. Recurrent acute biliary pancreatitis (ABP)
2. Acute cholecystitis
3. Uncomplicated biliary colic
4. Cholangitis
This will be evaluated using yes/no questions as part of a questionnaire up to 90 days after discharge. Patients will be asked to note every biliary event using questionnaires during the 3 month follow-up observational period following discharge.

Key secondary outcome(s))
The following are assessed using questionnaires and evaluation of medical records 90 days after discharge:
1. Number of biliary colics for each patient
2. Difficult of cholecystectomy
3. Rate of conversion to cholecystectomy
4. Total length of hospital stay
5. Need for ICU admission and total length of ICU stay
6. Organ failure
7. Biliary leakage

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Diagnosis of acute pancreatitis, with at least 2 of the following symptoms:
2.1. Upper abdominal pain
2.2. Serum lipase three times higher than the upper limit of normal and characteristic findings for acute pancreatitis on imaging
2.3. Serum amylase three times higher than the upper limit of normal and characteristic findings for acute pancreatitis on imaging
3. Mild biliary pancreatitis (no pancreatic necrosis, no transient or persistent organ failure (>48 hours)) according to the revised Atlanta classification
4. Any of the following 3 definitions of biliary pancreatitis:
4.1. Diagnosis of gallstones or sludge on imaging
4.2. Dilated common bile duct on ultrasound (>8 mm in patients aged 75 years old and under, or >10 mm in patients over 75 years old) with the absence of gallstones or sludge in the gallbladder
4.3. Alanine aminotransferase level >2 times higher than normal values, with alanine aminotransferase levels greater than aspartate aminotransferase levels
5. ERCP/ES either during the index admission or in the medical history without complication (added 01/02/2019)
6. Signed written informed consent

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Poor physical status
2. American Society of Anesthesiologists (ASA) class III in patients over 75 years old
3. ASA class IV or V in patients 75 years old or younger
4. Continuous alcohol abuse
5. Chronic pancreatitis
6. Pregnancy
7. Previous sphincterotomy (removed 01/02/2019)
8. Previous cholecystectomy

Date of first enrolment
01/03/2019

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
Hungary

Romania

Study participating centre
University of Pecs Medical School Institute for Translational Medicine
Szigeti str 12.
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Study participating centre
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Sponsor information

Organisation
University of Pécs

Organisation
Hungarian Academy of Sciences, Momentum Grant

Organisation
GINOP 2.3.2.-15 'Stay Alive'

Organisation
University of Pecs

ROR
https://ror.org/037b5pv06

Funder(s)

Funder type
University/education

Funder Name
Általános Orvostudományi Kar, Pécsi Tudományegyetem

Alternative Name(s)
Medizinische Fakultät, Universität Pécs, PTE Általános Orvostudományi Kar, Medizinische Fakultät, Universität Pécs, Medical School, University of Pécs, ÁOK, PTE, UP MS, PTE ÁOK

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Hungary

Results and Publications

Individual participant data (IPD) sharing plan
The data from this study is available upon request from the principal investigators (Dezső Kelemen MD, PhD, University of Pécs, Medical School, kelemende@gmail.com and Levente-Pal Kucserik MD, UMF Targu Mures, k.levente.p@gmail.com). The questionnaires, the eCFR (raw data) and the analyzed data can be available for other laboratories by reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes