ISRCTN13517695 https://doi.org/10.1186/ISRCTN13517695

Preventive pancreatic stents in the management of acute biliary pancreatitis

Submission date 13/11/2014	**Recruitment status** Suspended	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 09/12/2014	**Overall study status** Completed	
Last Edited 04/05/2020	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Acute inflammation of the pancreas (acute pancreatitis) can be a severe or even life-threatening disease. Gallstones are the most common cause, which is called acute biliary pancreatitis (ABP). If you have co-existing infection and inflammation of the biliary tree (acute cholangitis) and/or persistent biliary obstruction (cholestasis), an endoscopic procedure (called ERCP) is beneficial which includes clearance of the biliary tree. Severe complications occur in 10-20% of all cases despite endoscopic treatment, probably because the opening of the pancreatic duct is simultaneously obstructed. Theoretically when we temporarily place a small plastic tube (a preventive pancreatic stent or PPS) into the pancreatic duct, it keeps it open until the inflammation resolves and the risk of pancreatic duct obstruction diminishes. Our goal is to show the positive effect of PPS placement added to the standard endoscopic therapy. The study findings should help to optimize the treatment of this severe disease.

Who can participate?
Patients aged 18 or over with cholangitis and/or cholestasis.

What does the study involve?
Participants will be randomly allocated to receive either the standard endoscopic treatment or PPS placement added to the standard treatment. Every patient will be hospitalized and receive similar medical treatment. Clinical and laboratory data will be collected for outcome measures.

What are the possible benefits and risks of participating?
Patients who receive PPSs may have better overall outcome and quicker symptom resolution compared to the standard treatment. The main risk of placing a PPS is unsuccessful placement which might cause an even worse outcome; therefore only very experienced endoscopists are involved in this study.

Where is the study run from?
The PREPAST study is set up by the Hungarian Pancreatic Study Group in Szeged, Hungary. All procedures will be performed at the participating medical centers.

When is the study starting and how long is expected to run for?
It is anticipated that recruitment will start in early 2015. Based on our preliminary calculations the total target number of participants will be enrolled over a 4-year period; however, if more centers join in the study it will be shorter.

Who is funding the study?
The Hungarian Pancreatic Study Group (HPSG).

Who is the main contact?
Zsolt Dubravcsik MD
dubravcsikzs@gmail.com
Professor Péter Hegyi MD, PhD,
hegyi2009@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Zsolt Dubravcsik

Contact details
Nyíri út 38
Kecskemet
Hungary
6000
+36 (0) 30 9599257
dubravcsikzs@gmail.com

Type(s)
Scientific

Contact name
Dr Peter Hegyi

Contact details
University of Szeged
Dugonics Ter 13
Szeged
Hungary
6720
+36 (0)70 3751031
hegyi2009@gmail.com

Additional identifiers

Protocol serial number
PREPAST

Study information

Scientific Title
Preventive pancreatic stents in the management of acute biliary pancreatitis: PREPAST, a prospective multicenter randomized controlled trial (Hungarian Pancreatic Study Group)

Acronym
PREPAST

Study objectives
We hypothesise that placement of a preventive pancreatic stent (PPS) at the course of early endoscopic retrograde cholangiopancreatography (ERCP), endoscopic sphincterotomy (ES) and stone extraction reduces morbidity and mortality in acute biliary pancreatitis (ABP) patients with cholangitis and/or cholestasis compared to the standard of care ERCP, ES and stone extraction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Medical Ethics Committee, Hungary, 13/10/2014, ref.: ETT TUKEB 030174/2014/OTIG

Study design
Prospective randomized controlled multicenter trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute biliary pancreatitis (ABP)

Interventions
Patients with ABP and co-existing acute cholangitis will recieve early endoscopic intervention (group A). Patients in group A will be randomized either into group A1 (ERCP, ES treatment) or into group A2 (ERCP, ES + PPS treatment). Patients with ABP but without evidence of acute cholangitis will be assessed for evidence of cholestasis. Patients without co-existing acute cholangitis but evidence of cholestasis will be randomized to receive conservative treatment or early ERCP, ES and bile duct clearance or early ERCP, ES, bile duct clearance plus PPS insertion (group B). Patients receiving conservative treatment will be assessed at 24 hours after randomization (no later than 72 hours from the onset of pain) for clinical and laboratory signs of persistent cholestasis. If this is present patients will recieve ERCP, ES and bile duct clearance and their data will be collected separately. Patients in group B will be randomized either into group B0 (conservative treatment), into group B1 (ERCP, ES treatment) or into group B2 (ERCP, ES + PPS treatment). Patients without signs of cholestasis (and acute cholangitis) will receive conservative treatment (group C), and will not be randomized.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Composite of mortality and major morbidity (described as a complicated course of ABP). A complicated course is described as any of the following three:
1. Moderate and severe acute pancreatitis (including temporary and persistent organ failure)
2. Any complications including systemic (exacerbation of pre-existing co-morbidity) and all local complications (acute peripancreatic fluid collection without tendency of spontaneous resolution, pancreatic pseudocyst, acute necrotic collection, walled-off necrosis) of AP as described in the revised Atlanta classification
3. Mortality

Key secondary outcome(s))
Secondary endpoints related to ABP outcome:
1. Multi-organ failure in each subgroup
2. Mortality rate in each subgroup
3. Pain score on admission, 24 and 72 hours after ERCP (or after randomization in group B1 conservative treatment group)
4. New onset of sepsis
5. The proportion of patients with severe course of ABP
6. The proportion of patients with severe organ failure requiring respiratory support (mechanical ventilation) and/or cardiac support (vasopressors) and/or renal support (haemodialysis)

Secondary endpoints related to endoscopic treatment:
1. PPS insertion success rate
2. Consequences of attempted but failed pancreatic stenting (this subgroup will be analyzed separately)
3. Endoscopists experience on PPS success rate and ABP outcome
4. The influence of the endoscopic technique used on the outcome of ABP
5. Influence of patient and procedure related risk factors of post-ERCP pancreatitis (published by the European Society of Gastrointestinal Endoscopy ESGE) on the outcome of ABP patients who underwent ERCP and on the success rate of PPS insertion

Completion date
31/08/2022

Eligibility

Key inclusion criteria
1. Age ≥ 18 years (either sex)
2. Diagnosis of acute biliary pancreatitis
3. Written informed consent
4. Possibility of performing ERCP within 48 hours calculated from the onset of pain

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnancy
2. Acute pancreatitis due to alcohol, hyperlipidaemia, malignancy or post-ERCP pancreatitis
3. Pain onset >48 hours
4. Abscence of abdominal pain (the onset cannot be assessed)
5. Liver cirrhosis Child score C
6. Pancreatic fluid collections or necrosis on initial imaging at presentation
7. INR>1.6 and uncorrectable by the time of ERCP
8. Previous endoscopic sphincterotomy

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Hungary

Study participating centre
University of Szeged
1st Department of Internal Medicine
Dugonics Ter 13
Szeged
Hungary
6720

Study participating centre
County Hospital
Department of Gatsroenterology
Nyiri ut 38.
Kecskemet
Hungary
6000

Study participating centre

University of Pecs
1st. Department of Internal Medicine
Ifjusag ut 13.
Pecs
Hungary
7624

Study participating centre
National Health Center
Department of Gastroenterology
Podmaniczky u. 111.
Budapest
Hungary
1062

Sponsor information

Organisation
Hungarian Pancreatic Study Group (HPSG) (Hungary)

Funder(s)

Funder type
Research organisation

Funder Name
Hungarian Pancreatic Study Group (HPSG) (Hungary)

Funder Name
European Social Fund

Alternative Name(s)
European Social Fund, Европейският социален фонд, Европейският социален фонд плюс, Fondo Social Europeo, Fondo Social Europeo Plus, Ευρωπαϊκό Κοινωνικό Ταμείο, Ευρωπαϊκό Κοινωνικό Ταμείο+, Ciste Sóisialta na hEorpa Plus, Ciste Sóisialta na hEorpa, ESF, ESF+, ΕΚΦ, ΕΚΦ+, FSE, FSE+, EKT, EKT+, CSE, CSE+

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
European Union

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes