ISRCTN11803209 https://doi.org/10.1186/ISRCTN11803209

A retrospective chart review of severe acute hyperlipidemic pancreatitis

Submission date
05/04/2017

Recruitment status
No longer recruiting

Registration date
25/04/2017

Overall study status
Completed

Last Edited
14/08/2019

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pancreatitis is a condition where the pancreas becomes inflamed (swollen). It can cause severe pain and illness. Pancreatitis can require hospitalisation. If it is severe enough, some patient have to be admitted to the intensive care unit. Hyperlipidemic severe acute pancreatitis (HL-SAP) can occur when a patient has high cholesterol or fats in the blood and pancreatitis. There is no unified way for treating HL-SAP but it is usually treated the conventional way, through fluids, nutrition, or treating the underlying cause (such as gallstones or cutting out alcohol). There is some anecdotal evidence that penta-therapy was used to treat hyperlipidemic severe acute pancreatitis (HL-SAP) in Shanghai China in the past. Penta-therapy consists of traditional Chinese medicine, blood purification, insulin (to control blood sugar), antihyperlipidemic agents (medicines to lower the fat in the blood), and heparin (prevents blood clots). The purpose of this study is to evaluate the efficacy of penta-therapy for HL-SAP.

Who can participate?
Adults aged 18 to 85 who were hospitalised for pancreatitis between January 2007 and December 2016.

What does the study involve?
Participants are allocated to one of two groups based on the treatment they received while they were hospitalised in the intensive care unit. Those who received the conventional treatment are compared to those who received penta-therapy. Participants are assessed for their overall condition, organs, severity of the pancreatitis and are followed up through telephone interviews to evaluate their rate of recurrence, overall mortality, hospital stays, operation rates, and complications.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
Shanghai General Hospital (China)

When is the study starting and how long is it expected to run for?
January 2017 to April 2017

Who is funding the study?
Investigator initiated and funded (China)

Who is the main contact?
Dr Rulian Wang

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRIC-D-17-00373

Study information

Scientific Title
Penta-therapy for severe acute hyperlipidemic pancreatitis: a retrospective chart review

Study objectives
The addition of penta-therapy to conventional treatment for hyperlipidemic severe acute pancreatitis (HL-SAP) may be superior to conventional treatment alone for improvement of serum biomarkers and clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Shanghai General Hospital Institutional Review Board, 07/04/2017, ref: [2017]20

Study design
Retrospective observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Pancreatitis

Interventions
This study is a retrospective study of patients who were hospitalised in the intensive care unit between January 2007 and December 2016. Participants are assigned to one of two groups based on the treatment they received while they were hospitalised.

Control group: Participants in this group received conventional treatment during their hospitalisation. Conventional treatment includes aggressive fluid resuscitation, oxygen supplementation, gastrointestinal decompression, insulin and/or heparin treatment, oral antihyperlipidemic therapy, dietary interventions, nutritional support, prophylactic antibiotics, and drainage of peripancreatic abscesses.

Experiment group: Participants in this group receive conventional treatment as well as the experimental protocol (the penta-therapy) which consists of blood purification, antihyperlipidemic agents, low-molecular-weight heparin, insulin, and covering the whole abdomen with Pixiao (a traditional Chinese medicine). Blood purification is achieved by means of plasma exchange (PE). Antihyperlipdemic agents, including fibrates, niacin, statins and (i.e. gemfibrozil, fenofibrate, clofibrate), are used to decrease blood lipid to avoid recurrent of acute pancreatitis. Low molecular weight heparin are injected subcutaneous. Intensive care doctors provide the penta therapy to the patients.

Participants are evaluated for their overall condition, organ function, severity of pancreatitis, pancreatitis image level and serum biomarkers.

Participants are contacted by telephone for follow up and this includes assessing rate of recurrence, overall mortality, hospital length of stay, operation rate, local complications and systematic complications.

Intervention Type
Mixed

Primary outcome measure
1. Patient's condition is measured using the APACHE II score at date of admission
2. Organ function is measured using the SOFA score at date of admission
3. Pancreatitis severity is measured using the Ranson score at date of admission
4. Pancreatitis image level is measured using the CT severity index at date of admission
5. Laboratory findings is measured using serum biomarkers at date of admission and seven days

Secondary outcome measures
1. Rate of recurrence is measured using patient interviews during the study period
2. Overall mortality is measured by reviewing patient notes during the study period
3. Hospital length of stay is measured by reviewing patient notes during the study period
4. Operation rate is measured by reviewing patient notes during the study period
5. Local complications and systemic complications are measured byreviewing patient notes during the study period

Overall study start date
01/02/2017

Completion date
01/04/2017

Eligibility

Key inclusion criteria
1. Aged 18 to 85 years old
2. Presented within 72 hours of the onset of pain
3. AP diagnosis made according to the Atlanta classification
4. Triglyceride levels of >1,000 mg/dL(11.3mmol/L),500mg/dL(5.65mmol/L) with lipidic plasma and no other obvious cause of pancreatitis found for HL-SAP patients
5. Agree to participate and provide signed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
88

Total final enrolment

Key exclusion criteria
1. Flare-up of chronic pancreatitis
2. History of allergies to heparin or insulin
3. Disseminated intravascular coagulation or severe active bleeding
4. Respiratory failure, severe systemic circulatory failure, coma, or other life-threatening symptoms that were difficult to reverse and who were predicted to die within 24 hours (with full-fluid resuscitation and norepinephrine usage at a dose of 25 mg/ min, with a systolic blood pressure <90 mm Hg and serum pH values <7.0)
5. Patients who were delayed getting treatment because of some reason
6. Patients who presented with APACHE II score <3

Date of first enrolment
02/02/2017

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
China

Study participating centre
Shanghai General Hospital
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Shanghai Jiao Tong University School of Medicine
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Sponsor information

Organisation
Shanghai General Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04a46mh28

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/08/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2018	14/08/2019	Yes	No