

# A retrospective chart review of severe acute hyperlipidemic pancreatitis

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<b>Registration date</b> 25/04/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/08/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> 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 patients 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

**Contact name**  
Dr Ruilan Wang

**Contact details**  
Department of ICU  
Shanghai General Hospital  
Shanghai Jiao Tong University School of medicine  
No. 650 New Songjiang Road  
Songjiang  
Shanghai  
China  
201600

## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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). Antihyperlipidemic 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(s)**

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

## **Key secondary outcome(s)**

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 by reviewing patient notes during the study period

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

88

**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**

Shanghai General Hospital

Shanghai Jiao Tong University School of Medicine

No. 650 New Songjiang Road

Songjiang

Shanghai

China

201600

## Sponsor information

**Organisation**

Shanghai General Hospital

**ROR**

<https://ror.org/04a46mh28>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/10/2018	14/08/2019	Yes	No