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Testing different doses of an anti-inflammatory medicine called ulinastatin given early to people with severe pancreas inflammation

Submission date
12/10/2026

Recruitment status
Recruiting

Registration date
13/10/2026

Overall study status
Ongoing

Last Edited
13/10/2026

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

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Study information

Scientific Title
Efficacy and optimal dosage of early intravenous ulinastatin therapy in patients with early hyperinflammatory acute pancreatitis: a multicenter, double-blind, bayesian multi-arm multi-stage randomized controlled trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/03/2026, Ethics Committee of Jinling Hospital (Official Military Name: Clinical Research Ethics Committee of the General Hospital of Eastern Theater Command, PLA No.305 East Zhongshan Road, Nanjing, 210000, China; +86 025-80863234; 622024350067@smail.nju.edu.cn), ref: 2026DZKY-035-02

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Dose comparison

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Efficacy and optimal dose of ulinastatin in patients with acute pancreatitis

Interventions
Participants will be randomized centrally 1:1:1:1 using an interactive web response system (IWRS) to intravenous ulinastatin 800,000 U, 400,000 U, 100,000 U, or placebo. Each dose was

diluted in 100 mL 0.9% sodium chloride and infused IV over 1–2 h every 8 h for 7 days (21 doses). If discharged early, treatment continued until the day before discharge. To maintain blinding of participants, investigators, and outcome assessors, the infusion bag were concealed with an opaque cover, and allocation information was not disclosed.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ulinastatin

Primary outcome(s)
1. Incidence of severe acute pancreatitis (SAP) within 14 days, defined as the occurrence of persistent (>48 h) organ failure; organ failure was defined as a single-system Sequential Organ Failure Assessment (SOFA-2) score ≥2, measured using electronic health records at the end of the study at day 14

Key secondary outcome(s)
1. Organ failure-free days within 14 days, defined as a single-system SOFA-2 score ≥2, measured using the SOFA-2 score at daily time points from randomization to 14 days

2. Incidence of new-onset organ failure, defined as a single-system SOFA-2 score ≥2, measured using the SOFA-2 score. Baseline organ function is documented at randomization. New-onset organ failure is that is absent at baseline and persists for >48 h; at daily time points from randomization to 14 days

3. Incidence of new receipt of organ support therapy, defined as initiation of one or more of the following in a participant who was not receiving that therapy at baseline: invasive mechanical ventilation, vasopressors, or renal replacement therapy, measured using electronic health records at 14 days

4. Incidence of infected pancreatic necrosis, defined according to the revised Atlanta classification as pancreatic and/or peripancreatic necrosis with documented infection, measured using electronic health records at 28 days

5. Systemic Inflammatory Response Syndrome (SIRS) free days, defined according to standard criteria as the presence of ≥2 of the following: Temperature >38°C or <36°C; Heart rate >90 beats /min; Respiratory rate >20 breaths/min or $PaCO_2$ <32 mmHg; White blood cell count >12,000 /mm^3 or <4,000/mm^3, or >10% band forms, measured using electronic health records at 14 days

6. Duration of ICU stay measured using ICU admission and discharge dates/times are prospectively recorded from the medical record. Duration of ICU stay is calculated as the time from ICU admission to the first ICU discharge; at 28 days

7. Overall mortality within 28 days measured using medical records, death certificates, and/or structured follow-up contacts at day 28

Completion date

31/10/2030

Eligibility

Key inclusion criteria
1. Age from 18 and 75 years
2. Diagnosed AP
3. Presence of Systemic Inflammatory Response Syndrome (SIRS) and/or CRP>150 mg/L
4. Anticipated initiation of the first dose within 48 hours of AP diagnosis

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Concurrent acute cholangitis requiring urgent Endoscopic Retrograde Cholangiopancreatography (ERCP)
2. Presence of a definite infection
3. Pancreatic tumor, pancreatic trauma, chronic pancreatitis, or history of pancreatic resection
4. Comorbid severe underlying diseases, such as heart failure, chronic liver disease, chronic kidney disease, severe diabetes, etc)
5. Pregnant or lactating, female subjects with a positive pregnancy test or subjects (or their partners) planning pregnancy within 6 months after the study ends
6. Known current participation or participation in another randomized controlled trial within the past 1 month
7. History of allergy to protease inhibitor
8. Other conditions considered by the investigator as unsuitable for inclusion

Date of first enrolment
01/11/2026

Date of final enrolment
31/10/2029

Locations

Countries of recruitment
China

Sponsor information

Organisation
Nanjing University

ROR
https://ror.org/01rxvg760

Funder(s)

Funder type

Funder Name
Techpool Bio-pharma Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available