

The effect of ulinastatin on sepsis-related organ failure in children

Submission date 21/08/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 29/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/08/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Sepsis is a serious medical condition that occurs when the body's response to an infection causes widespread inflammation, which can lead to damage in various organs. One of the ways sepsis can become more severe is through damage to the blood vessels, which can cause multiple organs to fail, a condition known as Multiple Organ Dysfunction Syndrome (MODS). Previous research suggests that a medication called ulinastatin might help by improving blood flow in tiny blood vessels, protecting the lungs, liver, and kidneys from sepsis-related damage, and potentially preventing organ failure. However, the existing evidence is not strong enough to confirm these benefits. Therefore, this study aims to test whether ulinastatin can reduce the chances of organ failure in children with sepsis and improve their overall recovery.

Who can participate?

Children with age between 28 days and 18 years old and diagnosed with sepsis.

What does the study involve?

Children participating in this study will be randomly assigned to one of two groups. The first group will receive ulinastatin through an intravenous (IV) drip every 8 hours for 7 days. The dosage will be adjusted based on the child's weight but will not exceed a certain limit. The second group will receive an equal amount of normal saline (a harmless fluid often used in medical treatments) as a placebo. By comparing the outcomes of the two groups, the researchers hope to determine whether ulinastatin is effective in reducing organ failure in septic children.

What are the possible benefits and risks of participating?

The administration of ulinastatin is likely to reduce the incidence of organ injury in septic children. The main risks include the potential low incidence of mild allergic reactions.

Where is the study run from?

Children's Hospital of Soochow University and takes place in 8 children's hospitals across China.

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

October 2023 to September 2026

Who is funding the study?
Guangdong Techpool Bio-pharma Co., Ltd. (China)

Who is the main contact?
1. Shuiyan Wu, doctor219@163.com
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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

The effect of ulinastatin on sepsis-related organ failure in children: a multicenter randomized controlled trial

Acronym

IMPROVING

Study objectives

Ulinastatin can reduce the incidence of sepsis-related organ failure and thus improve the prognosis of septic children

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 09/08/2024, Medical Ethics Committee of the Children's Hospital of Soochow University (No.92 Zhongnan Street, SIP, Suzhou, 215000, China; +86 0512-80693506; sdfetyyec@163.com), ref: 2024018

Study design

Multicenter randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment, Efficacy

Health condition(s) or problem(s) studied

Sepsis

Interventions

After completing screening measurements and acquiring written informed consent, eligible participants will be randomized in a 1:1 ratio to either the Ulinastatin group or the control group through an Interactive Web Response System (IWRS). The randomization code was computer-generated with random block size (4, 6 or 8) to ensure that allocation concealment could not be violated by guessing the allocation sequence at the end of each block, and the randomization was stratified by sites. Due to the nature of the treatment, blinding will not be applicable. The trial statistician will be blinded to the treatment code when performing the statistical analysis.

Ulinastatin group: received ulinastatin (20,000 U/kg/d [divided into three eight-hourly doses and administered one dose every 8-hour], maximum dose 300,000U for every 8-hour) through intravenous (IV) drip for 7 days.

Control group: received an equal amount of normal saline as a placebo.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Ulinastatin

Primary outcome(s)

Composite outcome of 28-day mortality and/or presence of at least one organ failure on day 7 after randomization (pSOFA ≥ 2 and/or Phoenix Sepsis Score ≥ 2 for each organ system)

Key secondary outcome(s)

The following secondary outcomes were measured using patients' hospitalization records and laboratory indexes:

1. Thrombomodulin levels on randomization days 0, 1, 2 and 7
2. Length of ICU stay to day 28 after randomization
3. Days of survival without life-support interventions to day 28 after randomization
4. Cytokine levels on randomization days 0, 1, 2 and 7
5. pSOFA and/or Phoenix Sepsis Score scores on randomization days 0, 1, 2 and 7
6. Blood lactate levels on randomization days 0, 1, 2 and 7
7. WBC, CRP, PCT, LDH levels on randomization days 0, 1, 2 and 7
8. 24-hour fluid output and intake within the first 7 days of randomization
9. Cumulative use of steroids within the first 7 days of randomization (equivalent to methylprednisolone)

Completion date

30/09/2026

Eligibility**Key inclusion criteria**

1. 28 days < age \leq 18 years
2. There is clear evidence of infection
3. Meet diagnostic criteria for sepsis: infection + pSOFA and/or Phoenix Sepsis Score (PSS) ≥ 2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

28 days

Upper age limit

18 years

Sex

All

Key exclusion criteria

1. Received immunomodulatory therapy within 2 months before enrollment, such as Xuebijing and thymosin
2. Use of high-dose non-steroidal anti-inflammatory drugs within two days before enrollment; The daily dose of glucocorticoids > 5 mg/kg or greater than 500 mg/day within two days before enrollment
3. Palliative treatment without enough life support treatment
4. Receive ulinastatin treatment prior to enrollment
5. Previous history of allergy to ulinastatin or any of its components
6. Children with terminal disease

Date of first enrolment

01/10/2024

Date of final enrolment

02/09/2026

Locations

Countries of recruitment

China

Study participating centre

Children's Hospital of Soochow University

No.92 Zhongnan street, SIP

Suzhou

China

215000

Study participating centre

Xi'an Children's Hospital

No. 69, Xijuyuan Lane, Xi'an City, Shaanxi Province

Xi'an

China

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Study participating centre

Beijing Children's Hospital, Capital Medical University

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Study participating centre

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Study participating centre

Anhui Provincial Children's Hospital
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Study participating centre

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Study participating centre

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Study participating centre

Children's Hospital of Nanjing Medical University
No. 72 Guangzhou Road, Nanjing
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Sponsor information

Organisation

Guangdong Techpool Bio-pharma Co., Ltd.

Funder(s)**Funder type**

Industry

Funder Name

Guangdong Techpool Bio-pharma Co., Ltd

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			28/08/2024	No	No