ISRCTN10478464 https://doi.org/10.1186/ISRCTN10478464

Nanoselenium as adjunctive therapy for patients with sepsis

Submission date
03/05/2026

Recruitment status
Recruiting

Registration date
05/05/2026

Overall study status
Ongoing

Last Edited
05/05/2026

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Sepsis is a life-threatening organ dysfunction caused by infection, with high incidence and death rates, posing a significant global public health burden. Current treatments primarily rely on anti-inflammatory therapy and organ support, yet death rates remain high. Immunomodulation may emerge as a new therapeutic direction. Our previous pilot trial found that nanoselenium supplementation enhances immune function, attenuates excessive inflammation, and protects against multiple organ dysfunction with a favorable safety profile in patients with sepsis. The present study aims to evaluate the effectiveness and safety of nanoselenium in critically ill patients with sepsis, with a particular focus on its effects on death rates, immune function, inflammatory markers, organ function, selenium levels, other relevant indicators, and safety outcomes.

Who can participate?
Sepsis patients aged 18 years and over admitted to the ICU

What does the study involve?
Participants are randomly assigned into two groups. The control group receives standard management supplemented with local clinical practice. The intervention group receives standard care supplemented with nanoselenium once daily for up to 10 days, unless discontinued earlier due to ICU discharge, death, or withdrawal, administered either orally or by feeding tube.

What are the possible benefits and risks of participating?
Participants will receive standard sepsis treatment and close monitoring. The intervention treatment may help improve immune function and patient condition, although this effect is still under investigation.
Adverse reactions related to the study drugs (nanoselenium) may occur, such as allergic reactions or abnormal liver function. The study will strictly monitor any adverse events and has a detailed risk management plan in place to ensure participant safety.

Where is the study run from?
The First Affiliated Hospital of Jinan University (China)

When is the study starting and how long is it expected to run for?
May 2026 to December 2028

Who is funding the study?
The First Affiliated Hospital of Jinan University (China)

Who is the main contact?
Dr Wan-Jie Gu, guwanjie@jnu.edu.cn

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Dr Wan-Jie Gu

ORCID ID
https://orcid.org/0000-0003-4923-8282

Contact details
613 Huangpu Avenue West
Guangzhou
China
510630
+86 (0)15850546835
guwanjie@jnu.edu.cn

Additional identifiers

Study information

Scientific Title
Standard care supplemented with nanoselenium versus standard care alone for sepsis: a randomized clinical trial

Study objectives
The present study aims to evaluate the efficacy and safety of nanoselenium in critically ill patients with sepsis, with a particular focus on its effects on mortality, immune function, inflammatory markers, organ function, selenium levels, other relevant indicators, and safety outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/04/2026, Scientific Research Ethics Committee of the First Affiliated Hospital of Jinan University (613 Huangpu Avenue West, Guangzhou, 510630, China; +86 (0)20-38688077; haiyanyin1867@126.com), ref: KY-2026-141

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care, Treatment

Study type(s)

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

Interventions
Eligible patients will be randomly assigned in a 1:1 ratio to receive either the standard care supplemented with nanoselenium or standard care alone. The random allocation sequence will be generated by an independent statistician using computer software, with random block sizes of 4 and 6. To conceal the allocation, the assignments will be placed in sequentially numbered, opaque, sealed envelopes. The envelopes will be kept securely and opened only by the study coordinator after a participant is formally enrolled. To ensure blinding, the researchers administering the interventions, the patients and their families, the outcome assessors, and the data statisticians will all be kept unaware of the group assignments throughout the trial.

Control group: receives standard management, following the 2021 international guidelines for sepsis and septic shock, supplemented with local clinical practice. Standard treatments included early administration of appropriate antibiotics, hemodynamic stabilization with fluid resuscitation and vasopressors, invasive or non-invasive mechanical ventilation when indicated, and extracorporeal organ support such as renal replacement therapy.

Intervention group: receives standard care supplemented with nanoselenium (total dose: 400μg) once daily at 8:00 AM for up to 10 days, unless discontinued earlier due to ICU discharge, death, or withdrawal. Nanoselenium was administered either orally or diluted in 0.9% sodium chloride via nasogastric or nasointestinal tube. The product was manufactured by Guangdong Jinan Established Selenium Source Nano Technology Research Institute Co., Ltd., China.

Intervention Type
Supplement

Primary outcome(s)
1. In-hospital mortality measured using the proportion of enrolled patients who die during hospital stay at until hospital discharge

Key secondary outcome(s)
1. Immune function measured using total lymphocyte count, T lymphocyte count, CD4+ T lymphocyte count, CD8+ T lymphocyte count, B lymphocyte count, NK lymphocyte count at days 1, 4, 7, and 10 after randomization

2. Inflammatory markers measured using L-6, CRP, PCT, white blood cell count, neutrophil count, and serum amyloid protein at days 1, 4, 7, and 10 after randomization

3. Organ function measured using Sequential Organ Failure Assessment (SOFA) and Acute Physiology and Chronic Health Evaluation II (APACHE II) at days 1, 4, 7, and 10 after randomization

4. ICU mortality measured using the proportion of enrolled patients who die during ICU stay at until ICU discharge

5. ICU and hospital length of stay measured using the total time from ICU/hospital admission to discharge at until ICU/hospital discharge/death

6. Duration of mechanical ventilation measured using the accumulated time with invasive mechanical ventilatory support at until ICU discharge/death

7. Selenium levels measured using blood and urine samples at days 1, 4, 7, and 10 after randomization

8. Safety measured using liver function (ALT, AST, total bilirubin), adverse drug reactions such as diarrhea (watery stools), dermatitis/rash, etc, at days 1, 4, 7, and 10 after randomization

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Meet the criteria for sepsis according to the Sepsis-3 definition
3. Expected ICU length of stay > 48 hours
4. Written informed consent obtained from the patient or their legally authorized representative

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Pregnant or breastfeeding women
2. Current use of selenium supplements or known allergy or intolerance to selenium preparations
3. Chronic renal insufficiency requiring regular dialysis
4. Severe hepatic insufficiency (Child-Pugh class C) or acute liver failure
5. Next of kin expressing a wish to withdraw life-sustaining treatment or initiate hospice care
6. Expected survival <3 days
7. Active hematologic malignancy
8. History of organ or bone marrow transplantation
9. History of cardiopulmonary resuscitation (CPR) within 72 hours prior to signing informed consent
10. Inability to obtain informed consent from a legally authorized representative, or explicit refusal to sign informed consent

Date of first enrolment
01/05/2026

Date of final enrolment
01/12/2028

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Jinan University
613 Huangpu Avenue West
Guangzhou
China
510630

Study participating centre
Guangzhou Red Cross Hospital of Jinan University
396 Tongfu Middle Road
Guangzhou
China
510220

Sponsor information

Organisation
First Affiliated Hospital of Jinan University

ROR
https://ror.org/05d5vvz89

Funder(s)

Funder type

Funder Name
First Affiliated Hospital of Jinan University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available