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Nanoselenium combined with glutamine versus glutamine alone for sepsis

Submission date
29/12/2025

Recruitment status
Recruiting

Registration date
06/01/2026

Overall study status
Ongoing

Last Edited
05/01/2026

Condition category
Infections and Infestations

[X] 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. Glutamine is an important energy source for immune cells, and selenium is a key trace element with antioxidant and immunomodulatory functions. This study aims to investigate the effects of nanoselenium combined with glutamine compared to glutamine alone on immune function, inflammatory response, organ function, intestinal mucosal barrier, and clinical outcomes in sepsis patients, with the goal of identifying a safer and more effective treatment strategy.

Who can participate?
Adult sepsis patients admitted to the ICU.

What does the study involve?
This is a single-center, randomized controlled trial. The plan is to recruit 120 eligible patients, randomly assigned into two groups of 60 each.
Control group: receives intravenous infusion of alanyl-glutamine injection alone (50 ml [10 g] alanyl-glutamine injection adding to 200 ml of 5% glucose), twice daily, for 7 days or until ICU discharge/death.
Intervention group: receives glutamine treatment as above, plus oral or nasogastric /nasointestinal administration of nanoselenium capsules (6 capsules/day, total selenium dose: 600 μg), once daily, for 7 days or until ICU discharge/death.
During the study, patient blood and urine samples will be collected to assess immune function, inflammatory markers, organ function, intestinal barrier function, selenium levels, and other relevant indicators. Clinical outcome data will also be recorded.

What are the possible benefits and risks of participating?
Possible benefits: 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.
Possible risks: Adverse reactions related to the study drugs (glutamine, 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?
January 2026 to December 2027

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Nanoselenium combined with glutamine versus Glutamine alone for Sepsis (NGS): a randomized controlled trial

Acronym
NGS

Study objectives
The present study aims to evaluate the efficacy and safety of nanoselenium combined with glutamine versus glutamine alone in critically ill patients with sepsis, with particular focus on its effects on immune function, inflammatory markers, oxidative stress, organ function, intestinal barrier function, selenium levels, other relevant indicators, and clinical outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/11/2025, 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-2025-308

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 randomized to receive either the intervention or control in a 1:1 allocation ratio. 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 intravenous infusion of alanyl-glutamine injection alone (50 ml [10 g] alanyl-glutamine injection adding to 200 ml of 5% glucose), twice daily, for 7 days or until ICU discharge/death.

Intervention group: receives glutamine treatment as above, plus oral or nasogastric /nasointestinal administration of nanoselenium capsules (6 capsules/day, total selenium dose: 600μg), once daily, for 7 days or until ICU discharge/death.

Intervention Type

Supplement

Primary outcome(s)
1. Immune function measured using total lymphocyte count, T lymphocyte count, Th lymphocyte (CD4) count, Ts lymphocyte (CD8) count, B lymphocyte count, NK lymphocyte count, immunoglobulins (IgG, IgA, IgM), and complements (C3, C4) at days 1, 4, 7, and 10 after randomization

Key secondary outcome(s))
1. Inflammatory markers measured using TNF-α, IL-2, IL-6, IL-10, IFN-γ, CRP, PCT, white blood cell count, neutrophil count, and serum amyloid protein at days 1, 4, 7, and 10 after randomization

2. Organ function measured using oxygenation index (PaO2/FiO2), cardiac troponin (cTnI), serum creatinine, total bilirubin, platelet count, and lactate at days 1, 4, 7, and 10 after randomization

3. Intestinal barrier function measured using D-lactate and zonulin at days 1, 4, 7, and 10 after randomization

4. ICU and in-hospital mortality measured using the proportion of enrolled patients who die during ICU stay or hospital stay at until ICU/hospital 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

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Age ≥18 years old
2. Sepsis (as defined by Sepsis-3)
3. Expected to be admitted to the ICU for more than 48 hours

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Refusal to participate or failure to provide informed consent
2. Pregnancy or breastfeeding
3. Known allergy to selenium or glutamine
4. Malignancy
5. Severe hepatic or renal dysfunction (including liver failure or dialysis-dependent uremia)
6. Receipt of immunosuppressive therapy or organ transplantation within the past 6 months
7. Fasting

Date of first enrolment
15/01/2026

Date of final enrolment
15/12/2027

Locations

Countries of recruitment
China

Sponsor information

Organisation
First Affiliated Hospital of Jinan University

ROR
https://ror.org/05d5vvz89

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available