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Erythropoietin treatment for patients with sepsis and severe lung injury

Submission date
14/04/2026

Recruitment status
No longer recruiting

Registration date
15/04/2026

Overall study status
Completed

Last Edited
14/04/2026

Condition category
Respiratory

[_] 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 serious infection that can lead to acute respiratory distress syndrome, a severe lung condition that makes it difficult for patients to breathe and can be life-threatening. Recombinant human erythropoietin is a medicine that may have benefits beyond its usual clinical use. This study aims to find out whether adding recombinant human erythropoietin to standard treatment can improve outcomes in adult patients with sepsis-associated acute respiratory distress syndrome.

Who can participate?
Adults aged 18 years or older who are admitted to the Intensive Care Unit with sepsis-associated acute respiratory distress syndrome, require ventilator support and blood purification treatment, and are able to provide informed consent and complete study follow-up may be included.

What does the study involve?
Participants will be randomly assigned to 1 of 2 groups. Both groups will receive standard treatment for sepsis, including fluid resuscitation, antimicrobial therapy, vasoactive agents, anticoagulation therapy, mechanical ventilation, and blood purification treatment. One group will also receive recombinant human erythropoietin, while the other group will receive 0.9% sodium chloride placebo. The study will compare the two groups using routine clinical assessments, blood tests, blood gas analysis, hemodynamic monitoring, lung volume function measurements, duration of mechanical ventilation, and 28-day follow-up.

What are the possible benefits and risks of participating?
Participants may or may not benefit directly from taking part. The study may help improve future treatment for patients with sepsis-associated acute respiratory distress syndrome. Possible risks include discomfort from blood sampling and possible side effects related to the study treatment or standard intensive care treatment. All participants will continue to receive standard medical care.

Where is the study run from?
The study is run from the Department of Critical Care Medicine, Sir Run Run Hospital of Nanjing Medical University, Nanjing, Jiangsu, China.

When is the study starting and how long is it expected to run for?
The study started in March 2021 and completed enrolment in March 2023. The expected study duration is about 24 months.

Who is funding the study?
The study is funded by the Research Project on Elderly Health of Jiangsu Provincial Health Commission and the Jiangsu Provincial Health Commission Research Project.

Who is the main contact?
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Study information

Scientific Title
A randomized placebo-controlled trial in patients with sepsis-associated acute respiratory distress syndrome evaluating whether recombinant human erythropoietin added to standard therapy, compared with placebo plus standard therapy, improves oxygenation and lung function, reduces inflammatory marker levels, shortens the duration of mechanical ventilation, and reduces mortality

Acronym
EPO-SARDS

Study objectives
To evaluate the efficacy of recombinant human erythropoietin in adult patients with sepsis-associated acute respiratory distress syndrome by comparing it with placebo plus standard therapy in terms of hemodynamic parameters, blood gas indices, lung volume function, inflammatory marker levels, duration of mechanical ventilation, and 28-day mortality.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/03/2022, Ethics Committee of Sir Run Run Hospital of Nanjing Medical University (Ethics Committee Office, Outpatient Building, 4th Floor, No. 109 Longmian Avenue, Jiangning District, Nanjing, Jiangsu, China, Nanjing, 211166, China; +86 25-87115710 / 25-87115712; IRB@njmu.edu.cn), ref: 2022-SR-S037

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Sepsis-associated acute respiratory distress syndrome in adult intensive care unit patients requiring ventilatory support and blood purification treatment.

Interventions
Eligible adult patients with sepsis-associated acute respiratory distress syndrome will be randomly assigned in a 1:1 ratio, using a random number table based on the order of admission, to a placebo group or an erythropoietin group. All participants will receive standard treatment for sepsis, including fluid resuscitation, antimicrobial therapy, vasoactive agents, anticoagulation therapy, mechanical ventilation, and blood purification treatment. The placebo group will receive normal saline as placebo by intravenous infusion at 10 mL/h in addition to lung-protective ventilation. The erythropoietin group will receive recombinant human erythropoietin in addition to the same standard therapy and lung-protective ventilation, at a dose of 50–100 U /kg administered 2–3 times per week by intravenous or subcutaneous injection. Hemodynamic parameters, blood gas indices, lung volume function, and inflammatory marker levels will be assessed before treatment and on days 7 and 14 after treatment initiation. Duration of mechanical ventilation and 28-day mortality will also be compared between groups.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Recombinant human erythropoietin; 0.9% sodium chloride placebo

Primary outcome(s)
1. Duration of mechanical ventilation measured using clinical records at During hospitalization, assessed from treatment initiation to discontinuation of mechanical ventilation

2. All-cause mortality within 28 days of hospitalization measured using clinical follow-up and hospital records, with Kaplan-Meier survival analysis at Within 28 days of hospitalization

Key secondary outcome(s)
1. Heart rate measured using the PiCCO system at Before treatment, and on days 7 and 14 after treatment initiation

2. Mean arterial pressure measured using the PiCCO system at Before treatment, and on days 7 and 14 after treatment initiation

3. Partial pressure of oxygen measured using PaO2 measured by blood gas analysis at Before treatment, and on days 7 and 14 after treatment initiation

4. Partial pressure of carbon dioxide measured using PaCO2 measured by blood gas analysis at Before treatment, and on days 7 and 14 after treatment initiation

5. Oxygenation index measured using blood gas analysis at Before treatment, and on days 7 and 14 after treatment initiation

6. End-expiratory lung volume measured using CT plain scan analysis with volume calculation software at Before treatment, and on days 7 and 14 after treatment initiation

7. Functional residual capacity measured using CT plain scan analysis with volume calculation software at Before treatment, and on days 7 and 14 after treatment initiation

8. Tumor necrosis factor-alpha measured using Serum TNF-α measured using ELISA at Before enrollment, and on the mornings of days 7 and 14 of treatment

9. Interleukin-10 measured using Serum IL-10 measured using ELISA at Before enrollment, and on the mornings of days 7 and 14 of treatment

10. C-reactive protein measured using Serum CRP measured using ELISA at Before enrollment, and on the mornings of days 7 and 14 of treatment

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1.Adult patients aged 18 years or older
2.Admitted to the Intensive Care Unit of Shaw Hospital affiliated with Nanjing Medical University between March 2021 and March 2023
3.Clinical diagnosis of sepsis and acute respiratory distress syndrome according to the study diagnostic criteria
4.Required ventilator support and blood purification treatment
5.Able to comply with study procedures and had complete follow-up clinical data
6.Informed about the study and provided voluntary written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
100

Key exclusion criteria
1.Cardiogenic shock
2.Concurrent fungal or viral infections
3.Severe gastrointestinal, liver, or kidney failure
4.Coagulopathy
5.Malignant tumors
6.Hemodynamic instability or inability to maintain blood pressure with vasoactive drugs
7.Immune system deficiency

Date of first enrolment
01/03/2021

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
China

Sponsor information

Organisation
Sir Run Run Hospital of Nanjing Medical University

Funder(s)

Funder type

Funder Name
Research Project on Elderly Health of Jiangsu Provincial Health Commission

Funder Name
Jiangsu Provincial Health Commission Research Project

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available