Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

A clinical trial to compare the effectiveness of Allicin with placebo on survival of sepsis patients in intensive care units

Protocol summary

Study aim
To compare the effectiveness of Allicin with placebo on survival of sepsis patients in intensive care units

Design
This randomized and double-blind clinical trial with parallel and control groups will be conducted on 110 patients who will be randomly selected using the blocks.

Settings and conduct
Sepsis patients admitted to the intensive care unit to Imam Reza Hospital and Ghaem Hospital, Mashhad, Iran are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the Allicin and control will receive placebo. The participants and person responsible for data collection are blind to group allocation and the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years; diagnosis of sepsis due to lung infection; not pregnant; not breastfeeding. Exclusion criteria: Having Allicin allergies; having a history of hypotension; having gastrointestinal bleeding; having hypotension; taking warfarin; having immunodeficiency disorders; inability of patient to take oral medication; having hepatic failure; having renal failure; having a history of neuromuscular disorders.

Intervention groups
The intervention group will receive 90 mg capsules of Nicovid, which is derived from Organosulfur, orally every 6 hours for 7 days. The control group will receive placebo orally every 6 hours for 7 days.

Main outcome variables
Evaluation of SpO2 level, mortality rate, number of days dependent on ventilator, dependent on vasopressor rate, serum level of acute-phase proteins and incidence of respiratory distress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220508054780N3**
Registration date: **2023-12-01, 1402/09/10**
Registration timing: **prospective**

Last update: **2023-12-01, 1402/09/10**
Update count: **0**

Registration date
2023-12-01, 1402/09/10

Registrant information

Name
Benyamin Fazli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3802 2711

Email address
fazlib@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2025-01-20, 1403/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of Allicin with placebo on survival of sepsis patients in intensive care units

Public title
The effectiveness of Allicin on survival of sepsis patients in intensive care units
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Diagnosis of sepsis due to lung infection Not pregnant Not breastfeeding
Exclusion criteria:
Having Allicin allergies Having a history of hypotension Having gastrointestinal bleeding Having hypotension Taking warfarin Having immunodeficiency disorders Inability of patient to take oral medication Having hepatic failure Having renal failure Having a history of neuromuscular disorders
Age
From **18 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be simple randomly assigned to two groups using the blocks and opaque envelopes will be used for concealment.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants and responsible for data collection are blind to group allocation and the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Approval date
2023-08-14, 1402/05/23
Ethics committee reference number
IR.MUMS.IRH.REC.1402.122

Health conditions studied

1

Description of health condition studied
Sepsis
ICD-10 code
A41.9
ICD-10 code description
Sepsis, unspecified organism

Primary outcomes

1

Description
SpO2 level
Timepoint
At the beginning of study and 7 days after intervention
Method of measurement
Pulse Oximeter

2

Description
Mortality rate
Timepoint
7 days after intervention
Method of measurement
Based on acute physiology and chronic health evaluation score (APACHE) II score

3

Description
Number of days dependent on ventilator
Timepoint
7 days after intervention
Method of measurement
The number of days the ventilator is used for the patient

Secondary outcomes

1

Description
Dependent on vasopressor rate
Timepoint
7 days after intervention
Method of measurement
The number of times the drug is prescribed to the patient

2

Description
Serum level of acute-phase proteins
Timepoint
At the beginning of study and 7 days after intervention
Method of measurement
C-Reactive Protein (CRP) test

3

Description
Incidence of respiratory distress
Timepoint
7 days after intervention
Method of measurement
Based on patient clinical trials

Intervention groups

1

Description
Intervention group: The intervention group will receive 90 mg capsules of Nicovid, which is derived from Organosulfur (Daghigh Tajhiz Ario, Tehran, Iran), orally every 6 hours for 7 days.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive placebo (There is no Organosulfur in it, but it has the same color, taste, structure and shape as Nicovid, produced by the research center of faculty of pharmacy, Mashhad University of Medical Sciences) orally every 6 hours for 7 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Benyamin Fazli
Street address
Imam Reza Hospital, Imam Reza Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2711
Email
fazlib@mums.ac.ir

2

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Benyamin Fazli
Street address
Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3840 0000
Email
fazlib@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Benyamin Fazli

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Imam Reza Hospital, Imam Reza Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3802 2711

Email
fazlib@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Benyamin Fazli

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Imam Reza Hospital, Imam Reza Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3802 2711

Email
fazlib@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Benyamin Fazli

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Imam Reza Hospital, Imam Reza Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3802 2711

Email
fazlib@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The research data obtained from the main outcomes of the study can be shared freely as 'open data'.

When the data will become available and for how long
6 months after publishing the results

To whom data/document is available
The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used
The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

From where data/document is obtainable
Benyamin Fazli provides the data analysis to the applicants via email: fazlib@mums.ac.ir

What processes are involved for a request to access data/document
Applicants can send emails to him and receive a response within a week.

Comments