

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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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

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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

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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
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Imam Reza Hospital, Imam Reza Square
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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