Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of the vitamin B1 effect on the outcomes of patients with sepsis under mechanical ventilation admitted to the general intensive care unit

Protocol summary

Study aim

Assessment of the vitamin B1 effect on the outcomes of patients with sepsis under mechanical ventilation in the general intensive care unit

Design

A double-blind, randomized clinical trial study with parallel groups and phase 3 on 56 patients. Randomization will be done with the block randomization method using Random allocation software.

Settings and conduct

This study will be conducted on patients with sepsis under mechanical ventilation admitted to the general intensive care unit of Urmia Imam Khomeini hospital. This study will be conducted as a double-blind study. The patient and the head of research will be blinded to the allocation of patients into intervention or placebo groups.

Participants/Inclusion and exclusion criteria

In this study, 56 patients under mechanical ventilation in the general intensive care unit will be included. The inclusion criteria will be patients over 18 years and sepsis patients. The patients with renal failure with a GFR of less than 15, vitamin B1 consumption during the last 15 days before hospitalization, hospitalization less than 4 days in ICU, and an indication for the administration of vitamin B1, such as alcohol poisoning will be excluded.

Intervention groups

In the intervention group, in addition to routine treatments, patients will receive oral vitamin B1 tablets (300 mg) on the second day of mechanical ventilation for up to 7 days. In the control group, patients will receive placebo tablets in addition to routine treatments.

Main outcome variables

duration of mechanical ventilation; SOFA score (Sequential Organ Failure Assessment); APACHE II score (Acute Physiology & Chronic Health Evaluation II).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220711055432N1**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**
Update count: **0**

Registration date

2022-09-10, 1401/06/19

Registrant information

Name

Mohammad Amin Valizade Hasanloei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

valizadeh.ma@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment of the vitamin B1 effect on the outcomes of patients with sepsis under mechanical ventilation admitted to the general intensive care unit

Public title
Assessment of the vitamin B1 effect on the outcomes of patients with sepsis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Sepsis patients Patients under mechanical ventilation for at least 24 hours Age above 18 years
Exclusion criteria:
Renal failure with a GFR of less than 15 Vitamin B1 consumption during the last 15 days before hospitalization Hospitalization less than 4 days in ICU Having an indication for the administration of vitamin B1, such as alcohol poisoning

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into intervention or placebo groups using the block randomization method based on generated numbers by Random allocation software. Thus, in this software, first, the number of groups and the total determined sample size will be entered, and then in the block section, the Block randomization method will be implemented. According to the total sample size (56 patients), 14 blocks of 4 will be used. Patients will be allocated to intervention or placebo groups based on generated numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be conducted as a double-blind clinical trial. The patient and the researcher evaluating the outcomes will be blind to the allocation of patients into intervention or placebo groups. In the first stage, none of the patients will know about their assignment to intervention or placebo groups (Vitamin B1 and placebo tablets will be similar in shape, size, and color). In the second stage, the anesthesiologist will prescribe the drug (other than the outcome assessor), so the table of computer-generated numbers will be given to the anesthesiologist. The anesthesiologist will enter the patients into groups according to the order of numbers. Finally, the name of groups will be encoded with the letters A and B.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Imam Khomeini Hospital, Urmia University of Medical Sciences
Street address
Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5715789397

Approval date
2021-12-15, 1400/09/24

Ethics committee reference number
IR.UMSU.HIMAM.REC.1401.016

Health conditions studied

1

Description of health condition studied
Sepsis

ICD-10 code
A41

ICD-10 code description
Other sepsis

Primary outcomes

1

Description
duration of mechanical ventilation

Timepoint
during a week after the intervention

Method of measurement
Days

2

Description
The Sequential Organ Failure Assessment (SOFA) Score

Timepoint
Before intervention and 1st, 3rd and 7th day after the intervention

Method of measurement
The Sequential Organ Failure Assessment (SOFA) index

3

Description
Acute Physiology and Chronic Health Evaluation (APACHE) II score
Timepoint
Before intervention and 1st, 3rd and 7th day after the intervention
Method of measurement
Acute Physiology and Chronic Health Evaluation (APACHE) II queationnaire

Secondary outcomes

1

Description
White blood cell count (WBC)
Timepoint
Before intervention and the 1st, 3rd and 7th day after the intervention
Method of measurement
Cell counter

2

Description
erythrocyte sedimentation rate (ESR)
Timepoint
Before intervention and the 1st, 3rd and 7th day after the intervention
Method of measurement
Flow Cytometry

3

Description
C-reactive protein (CRP)
Timepoint
Before intervention and the 1st, 3rd and 7th day after the intervention
Method of measurement
Elisa test

4

Description
Lactate dehydrogenase (LDH)
Timepoint
Before intervention and the 1st, 3rd and 7th day after the intervention
Method of measurement
Elisa test

5

Description
Neutrophil to lymphocyte ratio
Timepoint
Before intervention and the 1st, 3rd and 7th day after the intervention
Method of measurement
Blood sample

6

Description
Mortality
Timepoint
During hospitalization and 28 days after intervention
Method of measurement
Medical record/ phone call

Intervention groups

1

Description
Intervention group: Patients will receive oral vitamin B1 tablets (300 mg) on the second day of mechanical ventilation for up to 7 days in addition to routine treatments. The drug will be procured from Jalinous Pharmaceutical Company.
Category
Treatment - Other

2

Description
Control group: Patients will receive placebo tablets (300 mg) on the second day of mechanical ventilation for up to 7 days in addition to routine treatments. The placebo will be prepared by the pharmacy faculty of Urmia university of Medical Sciences.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Dr. Mohammad Amin Valizad Hasanlouei
Street address
Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
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5714783734
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Mohammad Amin Valizad Hasanlouei
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of patient information
Study Protocol
No - There is not 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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Not applicable
When the data will become available and for how long
Not applicable
To whom data/document is available
Researchers
Under which criteria data/document could be used
Not applicable
From where data/document is obtainable
Email address of the corresponding author: valizadeh.ma@umsu.ac.ir
What processes are involved for a request to access data/document
Email address of the corresponding author: valizadeh.ma@umsu.ac.ir
Comments