

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 questionnaire

## **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.

##### **City**

Urmia

##### **Province**

West Azarbaijan

##### **Postal code**

5715789397

##### **Phone**

+98 44 3345 7286

##### **Email**

valizadeh.ma@umsu.ac.ir

## 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.

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Phone**

+98 44 3223 4897

**Email**

gholizadeh.s@umsu.ac.ir

**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.

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715789397

**Phone**

+98 44 3345 7286

**Email**

valizadeh.ma@umsu.ac.ir

## Person responsible for scientific 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.

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715789397

**Phone**

+98 44 3345 7286

**Email**

valizadeh.ma@umsu.ac.ir

## Person responsible for updating data

**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.

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715789397

**Phone**

+98 44 3345 7286

**Email**

valizadeh.ma@umsu.ac.ir

## 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