Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of MitoQ versus placebo on clinical outcomes in patients with early septic shock: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of MitoQ versus placebo on clinical outcomes in patients with early septic shock

Design
This is a Phase III double-blind randomized clinical trial with a parallel control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Besat Hospital in Hamadan city, involving 40 eligible patients with early septic shock. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 65 years Premature septic shock Receive vasopressor for at least 6 and maximum for 24 hours Exclusion criteria: Pregnancy or breastfeeding Treated with other antioxidant and anti-inflammatory drugs Chronic liver or kidney disease

Intervention groups
Intervention group: Routine treatment with MitoQ capsules 10 mg every daily for 5 days Control group: Routine treatment plus placebo capsules daily for 5 days

Main outcome variables
Mortality rate, the number of patients under the mechanical ventilation, the number of days treated with mechanical ventilation, the number of patients needing vasopressor treatment, the number of days treated with vasopressors, the amount of vasopressor dose, changes in Sequential Organ Failure Assessment (SOFA), serum lactate level, CRP serum level, the need for kidney replacement therapy, the length of hospitalization in the intensive care unit and hospital

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N499**
Registration date: **2024-02-29, 1402/12/10**
Registration timing: **prospective**

Last update: **2024-02-29, 1402/12/10**
Update count: **0**

Registration date
2024-02-29, 1402/12/10

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-05, 1403/01/17

Expected recruitment end date
2025-03-07, 1403/12/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of MitoQ versus placebo on clinical outcomes in patients with early septic shock: a double-blind

randomized clinical trial

Public title
Effect of MitoQ versus placebo on clinical outcomes in patients with early septic shock
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years Premature septic shock Receive vasopressor for at least 6 and maximum for 24 hours
Exclusion criteria:
Pregnancy or breastfeeding Treated with other antioxidant and anti-inflammatory drugs Chronic liver or kidney disease
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2024-02-24, 1402/12/05
Ethics committee reference number
IR.UMSHA.REC.1402.725

Health conditions studied

1

Description of health condition studied
Early septic shock
ICD-10 code
R65.21
ICD-10 code description
Severe sepsis with septic shock

Primary outcomes

1

Description
Mortality rate
Timepoint
During the 28 days after intervention
Method of measurement
Based on medical records

2

Description
The number of patients under the mechanical ventilation
Timepoint
during the 28 days after the intervention
Method of measurement
Based on the medical record

3

Description
The number of days treated with mechanical ventilation
Timepoint
During the 28 days after the intervention
Method of measurement
Based on the medical record

4

Description
The number of patients needing vasopressor treatment
Timepoint
During the 28 days after the intervention
Method of measurement
Based on the medical records

5

Description
The number of days treated with vasopressors
Timepoint
During the 28 days after the intervention
Method of measurement
Based on the medical record

6

Description
The amount of vasopressor dose
Timepoint
During 5 days after the intervention
Method of measurement
Based on the medical record

7

Description
Changes in Sequential Organ Failure Assessment (SOFA)
Timepoint
During 5 days after intervention
Method of measurement
Based on medical records

8

Description
Serum lactate level
Timepoint
During 5 days after intervention
Method of measurement
By laboratory method

9

Description
CRP serum level
Timepoint
During 5 days after the intervention
Method of measurement
by laboratory method

10

Description
The need for kidney replacement therapy is all
Timepoint
During the 28 days after the intervention
Method of measurement
Based on the medical record

11

Description
The length of hospitalization in the intensive care unit and hospital
Timepoint
During the 28 days after the intervention
Method of measurement
Based on the medical record

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment with MitoQ capsules 10 mg every daily for 5 days
Category
Treatment - Drugs

2

Description
Control group: Routine treatment plus placebo capsules daily for 5 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital in Hamadan city
Full name of responsible person
Hadis Moradbaki
Street address
Besat Hospital, Shahed Square
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Email
hadismoradbaki@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Hadis Moradbaki

Position

Student of Pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Hamadan University of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

hadismoradbaki@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Maryam Mehrpooya

Position

Clinical Pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Hamadan University of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

m_mehrpooya2003@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available