

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

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Iran (Islamic Republic of)

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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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Early septic shock
ICD-10 code	R65.21
ICD-10 code description	Severe sepsis with septic shock
Primary outcomes	
<u>1</u>	
Description	Mortality rate
Timepoint	During the 28 days after intervention
Method of measurement	Based on medical records
<u>2</u>	
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
<u>3</u>	
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

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Hamadan

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6517838695

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

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

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Latest degree

Ph.D.

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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