

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of MitoQ versus placebo on serum the level of oxidative stress biomarkers 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 serum the level of oxidative stress biomarkers in patients with early septic shock

Design

This is a Phase III double-blind randomized clinical trial with a parallel control group involving 40 eligible patients, 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 20 mg every 12 hours for 5 days Control group: Routine treatment plus placebo capsules every 12 hours for 5 days

Main outcome variables

Primary outcome: The serum level of catalase enzyme, serum level of glutathione peroxidase enzyme, serum level of total antioxidant capacity, malonaldehyde serum level, serum levels of thiol groups, serum levels of iron and ferritin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N500**

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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-03, 1403/01/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of MitoQ versus placebo on serum the level of oxidative stress biomarkers in patients with early septic shock: a double-blind randomized clinical trial

Public title

Effect of MitoQ versus placebo on serum the level of oxidative stress biomarkers 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

2024-02-10, 1402/11/21

Ethics committee reference number

IR.UMSHA.REC.1402.688

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

The serum level of catalase enzyme

Timepoint

Before the intervention and on the third and fifth days after the intervention

Method of measurement

By Catalase Activity Assay (CAA)

2

Description

Serum level of glutathione peroxidase enzyme

Timepoint

Before the intervention and on the third and fifth days after the intervention

Method of measurement

By the Glutathione Peroxidase (GPx) Activity Assay

3

Description

Serum level of total antioxidant capacity

Timepoint

Before the intervention and on the third and fifth days after the intervention

Method of measurement

By the Total Antioxidant Capacity (TAC) Assay

4

Description

Malonaldehyde serum level

Timepoint

Before the intervention and on the third and fifth days after the intervention

Method of measurement

By the Oxygen Radical Absorbance Capacity (ORAC) assay

5

Description

Serum levels of thiol groups

Timepoint

Before the intervention and on the third and fifth days after the intervention

Method of measurement

By the Ellman's assay

6

Description

Serum levels of iron and ferritin

Timepoint

Before the intervention and on the third and fifth days after the intervention

Method of measurement

By the Total Iron-Binding Capacity (TIBC) Measurement and the enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment with MitoQ capsules 20 mg every 12 hours for 5 days

Category

Treatment - Drugs

2

Description

Control group: Routine treatment plus placebo capsules every 12 hours for 5 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan city

Full name of responsible person

Hanieh Hasani Pajoo

Street address

Besat Hospital, Shahed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hanieh Hasani Pajoo

Position

Student of Pharmacy

Latest degree

Medical doctor

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Latest degree

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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