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

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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
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Sponsors / Funding sources

1

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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
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Position
Student of Pharmacy

Latest degree
Medical doctor

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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