

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effects of coenzyme Q10 on oxidative stress, inflammatory factors, and outcome of septic patients

Protocol summary

Summary

Objective: Evaluation the effect of co-enzyme Q10 on oxidative stress, inflammatory biomarkers and outcome of patients with sepsis. Design: Randomized, double-blind, placebo controlled clinical trial Setting: Patients with sepsis hospitalized at intensive care unit of Alzahra hospital affiliated to Isfahan University of Medical Sciences. Major Inclusion and Exclusion criteria: All patients older than 18 years old who have at least two criteria of SIRS (Systemic Inflammatory Response Syndrome) plus proved or suspected infection and also APACHE II score greater than 15 will be enrolled in the study. Patients with coagulopathy and pregnancy will be excluded. Intervention: Eligible patients will be randomized to drug and placebo groups. Patients in drug group will be received co-enzyme Q10, 60 mg twice daily for 7 days. Both groups will be received standard sepsis treatment. Main outcome measures: Changes in bio marker levels before and after drug administration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504051497N4**

Registration date: **2015-07-06, 1394/04/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-06, 1394/04/15

Registrant information

Name

Sarah Mousavi

Name of organization / entity

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Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of coenzyme Q10 on oxidative stress, inflammatory factors, and outcome of septic patients

Public title

Evaluation the effecte of coenzyme Q10 in patients with sepsis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Critically ill patients with sepsis (proved or suspected infection) plus at least 2 criteria from following conditions: Body temperature >38.3 c or <36 c, Heart rate > 90 beat/min, Respiratory rate >20 breath/min or PaCO₂ < 32 mmHg, White blood cells (WBC) > 12000 cell/mm³, or < 4000 cell/mm³, or >10%

immature [band]cells, Sudden change of mental status, and Hypoglycemia (blood glucose<120 mg/dl in the absence of diabetes); APACHE II score ≥15 on admission day; Availability of oral route administration; Consent of the patients or their relatives. Exclusion criteria: Pregnancy; End-stage or DNR (Do Not Resuscitate) patients; Patients enrolled in other studies; Coagulopathy (INR>2)

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Block randomization will performed in random blocks of two to eight

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code

Approval date

2015-03-02, 1393/12/11

Ethics committee reference number

4/6450/3

Health conditions studied

1

Description of health condition studied

Sepsis/septic shock

ICD-10 code

R57.2 (Sep

ICD-10 code description

Septic shock

Primary outcomes

1

Description

Changes in biomarkers levels before and after intervention

Timepoint

Day 1, 3 and 7 of admission

Method of measurement

ELIZA Kit

Secondary outcomes

1

Description

Hospital lenght of stay

Timepoint

Until the end of hospital stay

Method of measurement

Day

2

Description

Duration of mechanical ventilation

Timepoint

Until extubation

Method of measurement

Day

3

Description

Mortality rate

Timepoint

Day 7 and 28

Method of measurement

Day

Intervention groups

1

Description

Patients in intervention group will receive co enzyme Q10 60 mg (two 30 mg capsules) (Nature made Co., USA) two times per day for 7 days. Both groups also will receive standard sepsis treatment based on international guidelines.

Category

Treatment - Drugs

2

Description

Patients in control group will receive placebo (which will produce by pharmacy faculty) two times per day for 7 days. Both groups also will receive standard sepsis treatment based on international guidelines.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Sarah Mousavi

Street address

Hezar Jerib avenue, Isfahan University of Medical Sciences, Alzahra Hospital

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Nematbakhsh

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Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Grant name

5005/4/3

Grant code / Reference number

193114

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Isfahan University of Medical Science

Full name of responsible person

Dr Sarah Mousavi

Position

PhD

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Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty