Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of coenzyme Q10 supplementation on inflammatory markers, oxidative stress factors and clinical outcomes in burned patients: a double-blind placebo-controlled randomized clinical trial

Protocol summary

Study aim
Determining the effect of coenzyme Q10 supplementation on inflammatory factors, oxidative stress and clinical outcomes of hospitalized burn patients

Design
A double-blind, randomized controlled clinical trial with parallel groups on 60 patients. Randomization using a valid website and 4-blocking method.

Settings and conduct
This clinical trial will be performed on patients admitted to Imam Musa Kazem Hospital. Q10 and placebo are given to patients in exactly the same packaging. Patients and researchers will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Burn Patients aged 18-65 years admitted to Imam Musa Kazem Hospital

Intervention groups
Three doses of 100 mg coenzyme Q10 per day in the intervention group Three doses of 100 mg placebo per day in the control group

Main outcome variables
Before and after the intervention, inflammatory status (ESR, CRP), WBC, oxidative stress indicators (TAC, TOS), BUN and creatinine, triglyceride and HDL, blood sugar and clinical indicators (body temperature and number of hospital days) will be evaluated.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201129049534N3**
Registration date: **2021-06-30, 1400/04/09**
Registration timing: **registered_while_recruiting**
Last update: **2021-06-30, 1400/04/09**
Update count: **0**

Registration date
2021-06-30, 1400/04/09

Registrant information

Name
Mohammad bagherniya

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-20, 1400/03/30

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of coenzyme Q10 supplementation on inflammatory markers, oxidative stress factors and clinical outcomes in burned patients: a double-blind placebo-controlled randomized clinical trial

Public title
"The effects of coenzyme Q10 supplementation on burn patients"

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 65-18 years Accept informed consent by the patient or his mobile Gastrointestinal tract with normal function Has a burn above 20% Proper fluid recovery in the first 24 hours and hemodynamic stability after 48 hours
Exclusion criteria:
• Patients who are hospitalized for less than 48 hours or do not have stable conditions to start oral or tube feeding. • Dissatisfaction of the patient or family. • Patients with cancer undergoing chemotherapy and cisplatin. Patients receiving warfarin. • Pregnancy Severe and progressive septic shock or sepsis Hypovolemic shock in the first 48 hours Patients who are expected to die within one week of admission. • Patients with a history of certain diseases such as congenital and immune disorders, cirrhosis and pancreatitis.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After sampling in an easy or accessible way, random allocation of samples is done using the blocking method (4 blocks based on age and sex) and individually. This is done using a reputable random number making website: https://www.sealedenvelope.com/simple-randomiser/v1/lists First, we identify one letter for each group, for example, group A) intervention group (group B), control group (and thus two groups named A and B will be formed and each research unit will be given a number according to the sample size of one A list of 60 people will be obtained, which will be placed in each group of 30 people. Using the website and considering the four blocks, a list consisting of the letters A and B will be prepared randomly. Each participant will be assigned to one of the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Q10 and placebo capsules are packaged and covered by Golden Life Company. The capsules will be exactly the same in shape, smell, color, size and will be coded A and B by someone other than the researcher. Patients and researchers will not be aware of the capsule type until the end of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Vice-Chancellor in Research Affairs - Medical University of Isfahan
Street address
Hezar-jerib Avenue, Isfahan University of Medical Sciences, School of Nutrition and Food Sciences
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-06-09, 1400/03/19
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.109

Health conditions studied

1

Description of health condition studied
burns
ICD-10 code
T30.0
ICD-10 code description
Burn of unspecified body region, unspecified degree

Primary outcomes

1

Description
C reactive Protein (CRP)
Timepoint
At baseline and end of the study
Method of measurement
ELISA test

2

Description
Erythrocyte sedimentation rate (ESR)
Timepoint
At baseline and end of the study
Method of measurement
ELISA test

3

Description
Total antioxidant capacity
Timepoint
At baseline and end f the study
Method of measurement
Commercial diagnostic kit

4

Description
Total oxidative stress
Timepoint
At baseline and end of the study
Method of measurement
Commercial diagnostic kit

5

Description
White blood cells (WBC)
Timepoint
At baseline and end of the study
Method of measurement
ELISA test

6

Description
Body temperature
Timepoint
At baseline and end of the study
Method of measurement
Measurement with a thermometer

7

Description
high-density lipoprotein (HDL)
Timepoint
At baseline and end of the study
Method of measurement
ELISA test

8

Description
triglycerides
Timepoint
At baseline and end of the study
Method of measurement
ELISA test

9

Description
fasting blood sugar (FBS)
Timepoint
At baseline and end of the study
Method of measurement
ELISA test

10

Description
Blood urea nitrogen
Timepoint
At baseline and end of the study
Method of measurement
ELISA test

11

Description
Creatinine
Timepoint
At baseline and end of the study
Method of measurement
ELISA test

Secondary outcomes

1

Description
28-day mortality rate
Timepoint
End of the study
Method of measurement
Mathematically dividing the number of dead people by the total number of people using hospital records or telephone follow-up

2

Description
Duration of hospitalization
Timepoint
End of the study
Method of measurement
Hospital records

Intervention groups

1

Description
Intervention group: 3 capsules of 100 mg of coenzyme Q10 supplement daily (3 times, one capsule of 100 mg each time, immediately after breakfast, lunch and dinner, a total of 300 mg of coenzyme Q10 daily) for 10 days. From Golden Life Trading Company
Category
Treatment - Drugs

2

Description
Control group: Control group: 3 100 mg placebo capsules daily (containing maltodextrin) (3 times, one 100 mg capsule each time, immediately after breakfast, lunch and dinner, in a daily dose of 300 mg) for 10 days. From Golden Life Trading Company
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Mousa Kazem Hospital
Full name of responsible person
zahra kiyani
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan 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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Bagherniya
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about the study will be published after the individuals are not identified and the project is completed.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
For further analysis
From where data/document is obtainable
Dr. Mohammad Bagherniya email: bagherniya@nutr.mui.ac.ir
What processes are involved for a request to access data/document
After reviewing the request and making it fully clear about the purposes of using the data, the data will be provided.
Comments