Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessment of the effect of Q10 supplementation on oxidative stress in mechanically Ventilated Traumatic patients admitted to intensive care unit of Urmia Imam Khomeini hospital

Protocol summary

Study aim

Determination of the Effect of Q10 Supplementation on Oxidative Stress in Traumatic Patients under Mechanical Ventilation admitted to intensive care unit of Urmia Imam Khomeini Hospital

Design

The study was a randomized double blind randomized clinical trial with the aim of determining the supplementation of Q10 co-enzyme for 7 days. 40 traumatic patients under mechanical ventilation were randomly assigned into intervention and placebo groups using random number table with simple random sampling.

Settings and conduct

Traumatic patients under mechanical ventilation in the intensive care unit of Urmia Imam Khomeini Hospital were randomly divided into intervention and placebo groups ,and were followed up for 7 days to assessing the outcomes. The study was double-blind. The patient and the investigator were unaware about the assignment of patients in the intervention or placebo groups. the Q10 supplement was given to the patients by a person other than the investigator .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Traumatic patient under mechanical ventilation; aged 18-65; admission for at least 7 days in ICU. Exclusion criteria: Contraindication of intestinal nutrition; Diabetes mellitus; Acute and chronic renal failure; GCS less than 9.

Intervention groups

Intervention group: co-enzyme Q 10 (100 mg) oral tablets every 4 hours (600 mg / day) for 7 days. Placebo: starch pill for 7 days.

Main outcome variables

Oxidative stress based on assessing the SOFA score (the sequential organ Failure Assessment Score) and Serum Interleukin Level 6(IL6).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171221037983N4**
Registration date: **2019-03-12, 1397/12/21**
Registration timing: **retrospective**

Last update: **2019-03-12, 1397/12/21**
Update count: **0**

Registration date

2019-03-12, 1397/12/21

Registrant information

Name

Mohammad Amin Valizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3346 9935

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2018-12-21, 1397/09/30

Trial completion date

2018-12-21, 1397/09/30

Scientific title
Assessment of the effect of Q10 supplementation on oxidative stress in mechanically Ventilated Traumatic patients admitted to intensive care unit of Urmia Imam Khomeini hospital

Public title
Q10 supplementation on oxidative stress

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Traumatic patients under mechanically Ventilation patients with 18-65 years patients admitted to intensive care unit for at least 7 days
Exclusion criteria:
No Contraindication of Intestinal Nutrition diabetic patients Acute and chronic renal failure GCS less than 9

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly assigned into two intervention and placebo groups using simple random sampling. In the first, a random number was selected from the random number table. in order to complete the sample size, the even and odd numbers were assigned into two intervention and placebo groups, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study was double-blind. The patient and the investigator were unaware about the assignment of patients in the intervention or placebo group. the Q10 supplement was given to the patients by a person other than the investigator .

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Imam Khomeini Hospital, Ershad street, Modarres Blv, Urmia, Iran
City
Urmia
Province
West Azarbaijan
Postal code
57157-89397

Approval date
2018-07-24, 1397/05/02

Ethics committee reference number
ir.umsu.rec.1397.134

Health conditions studied

1

Description of health condition studied
Traumatic patients under mechanical ventilation

ICD-10 code
S06.2X

ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Oxidative stress was evaluated based on SOFA score (the sequential organ failure assessment score) and serum IL-6 (IL6)

Timepoint
before and 7 days after intervention

Method of measurement
SOFA score was measured using a questionnaire and serum IL6 level based on ELISA method

Secondary outcomes

1

Description
mortality

Timepoint
seven days after intervention

Method of measurement
The death of the patient in hospital (yes/no)

2

Description
Mechanical ventilation duration

Timepoint
From admission to patient discharge

Method of measurement
Mechanical ventilation duration in days

3

Description
Duration of hospitalization
Timepoint
From admission to patient discharge
Method of measurement
duration of hospitalization in days

Intervention groups

1

Description
Intervention group: oral coenzyme Q10 100 mg every 4 hours (600 mg / day) for 7 days
Category
N/A

2

Description
Control group: Starch tablets for 7 days
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Imam Khomeini hospital
Full name of responsible person
Dr. Mohammad Amin Valizade Hasanlouei
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Imam Khomeini hospital; Ershad street; Modarres Blv; Urmia; Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
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Urmia University of Medical Sciences; Resalat street; Jahad square; Urmia; Iran
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Mohammad Amin Valizade Hasanlouei
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidentiality of patient information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable