

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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;
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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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Person responsible for updating data

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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