

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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)

##### Phone

+98 44 3346 9935

##### Email address

valizademohammadamin@gmail.com

##### 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

##### Street address

Imam Khomeini hospital; Ershad street; Modarres Blv;  
Urmia; Iran

##### City

Urmia

##### Province

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##### Postal code

57157-89397

##### Phone

+98 44 3345 9538

##### Fax

+98 77 3345 7278

##### Email

valizademohammadamin@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Iraj Mohebbi

##### Street address

Urmia University of Medical Sciences; Resalat street;  
Jahad square; Urmia; Iran

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

57147-83724

##### Phone

+98 44 3223 1930

##### Fax

+98 44 3222 9059

##### Email

Mohebbi.i@gmail.com

#### 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

##### Street address

Imam Khomeini hospital; ershad street; Modarres Blv;  
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## Person responsible for scientific inquiries

### Contact

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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