

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of effect of coenzyme q10 and aerobic exercise on inflammatory, oxidative state and cardiorespiratory fitness in patients with traumatic brain injury

#### Protocol summary

##### Summary

The purpose of the present study is to investigate the effect of coenzyme q10 and aerobic exercise on inflammatory, oxidative state and cardiorespiratory fitness in patients with traumatic brain injury. In this clinical trial study that double-blinded for patients and researchers, patients with Simple randomization separated into two group of 30: the control group with no intervention and intervention group will get coenzyme q10, and do aerobic exercise. They will be evaluated cognitively and functionally using FFS and FIM questionnaires. After an initial assessment, interventions begin. The intervention group will receive 2.5 mg/kg/day Coenzyme Q10 for 3 months and also will do exercise 60-90 minutes, three times a week for 12 weeks. Burce protocol for the cardiopulmonary function was used and respiratory gas analyzer used for respiratory gases. Before and after the study Blood samples will be taken to measure inflammatory factors: IL-6 and hs- CRP. Also, total antioxidant capacity, Malondialdehyde and Glutathione peroxidase will be measured. inclusion: History of Traumatic Brain Injury 6 months ago, 18-65 years old and ability to cycling to do exercise. exclusion: Severe behavioral, physical and cognitive status preventing completing the study, Failure to cooperate until the end of the study, smoking and Drug addiction.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017071626805N2**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-11-19, 1396/08/28

##### Registrant information

###### Name

Samira Mis Ghavam

###### Name of organization / entity

Ilam University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 84 3222 7150

###### Email address

ghavam-sm@medilam.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Ilam University of Medical Sciences

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-05-22, 1397/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effect of coenzyme q10 and aerobic exercise on inflammatory, oxidative state and cardiorespiratory fitness in patients with traumatic brain injury

##### Public title

Evaluation of effect of coenzyme q10 and aerobic

exercise on inflammatory, oxidative state and cardiorespiratory fitness in patients with traumatic brain injury

#### **Purpose**

Basic science

#### **Inclusion/Exclusion criteria**

Inclusion criteria: History of Traumatic Brain Injury 6 months ago; 18-65 years old; Stable clinical situation; Having a medical certificate proving participants' ability to do exercise test; Commitment to complete the study; Ability to understand speech commands to complete study and ability to cycling to do exercise. Exclusion criteria: Severe behavioral, physical and cognitive status preventing completing the study; chronic and systemic disease(cardiovascular, pulmonary...); Failure to cooperate until the end of the study; smoking and Drug addiction.

#### **Age**

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

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Ilam University of Medical Sciences

###### **Street address**

Ilam University of Medical Sciences, Banganjab, Pajuhesh Blvd., Ilam, Iran

###### **City**

Ilam

###### **Postal code**

6939177143

##### **Approval date**

2010-11-05, 1389/08/14

##### **Ethics committee reference number**

lr.medilam.rec.1396.77

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

traumatic brain injury

##### **ICD-10 code**

S06

##### **ICD-10 code description**

Intracranial injury

### **Primary outcomes**

#### **1**

##### **Description**

IL-6

##### **Timepoint**

before intervention and 6th week and 12th week after beginning of intervention

##### **Method of measurement**

The IL-6 will be measured by ELISA method and by the bender medsystem kit.

#### **2**

##### **Description**

Cardiac function

##### **Timepoint**

before intervention and 6th week and 12th week after beginning of intervention

##### **Method of measurement**

Cardiac function will be tested with Bruce protocol.

#### **3**

##### **Description**

respiratory gasses

##### **Timepoint**

before intervention and 6th week and 12th week after beginning of intervention

##### **Method of measurement**

respiratory gases automatically will be analyzed using Ultima Cardio2.

#### **4**

##### **Description**

hs-CRP

##### **Timepoint**

before intervention and 6th week and 12th week after beginning of intervention

##### **Method of measurement**

hs-CRP will be measured by ELISA method and by the bender medsystem kit.

#### **5**

##### **Description**

malondialdehyde

##### **Timepoint**

before intervention and 6th week and 12th week after beginning of intervention

## Method of measurement

Levels of malondialdehyde will be measured by the Randox kit.

## 6

### Description

total antioxidant capacity

### Timepoint

before intervention and 6th week and 12th week after beginning of intervention

### Method of measurement

total antioxidant capacity will be measured by the Randox kit.

## 7

### Description

glutathione peroxidase

### Timepoint

before intervention and 6th week and 12th week after beginning of intervention

### Method of measurement

glutathione peroxidase will be measured by the Randox kit.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: with no intervention.

#### Category

N/A

### 2

#### Description

Intervention group: the intervention group will receive 2.5 mg/kg/day Coenzyme Q10 for 3 months and they will do exercise 60-90 minutes, three times a week for 12 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dr. Hafezi Pathology Clinic

##### Full name of responsible person

##### Street address

next to the Red Crescent, 22-Bahman Sq., Ilam, Iran

##### City

Ilam

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Ilam University of Medical Sciences

##### Full name of responsible person

Dr. Behzad Badakhsh

##### Street address

Vice chancellor for research and technology, Ilam University of Medical Sciences, Banganjab, Pajuhesh Blvd., Ilam, Iran

##### City

Ilam

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice Chancellor for research of Ilam 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

Ilam University of Medical Sciences

##### Full name of responsible person

Asghar Rahmani

##### Position

GP, Member of Student Research Committee of Ilam University of Medical Sciences

##### Other areas of specialty/work

##### Street address

Research Committee of Ilam University of Medical Sciences, Medical School, Ilam University of Medical Sciences, Banganjab, Pajuhesh Blvd., Ilam, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ilam University of Medical Sciences

**Full name of responsible person**

Samira Mis Gavam

**Position**

Faculty member, Cardiologist

**Other areas of specialty/work****Street address**

Vice chancellor for research and technology, Ilam University of Medical Sciences, Banganjab, Pajuhesh Blvd., Ilam, Iran

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## 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*