Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 scienece

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

Ir.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 begining 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 begining 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 begining of intervention

Method of measurement

respiratory gases automaticly will be analyzed using Ultima CardiO2.

4

Description

hs-CRP

Timepoint

before intervention and 6th week and 12th week after begining 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 begining 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 begining 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 begining 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
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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
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Research Committee of Ilam University of Medical Sciences, Medical School, 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