Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of coenzyme Q10 on brain growth factor and interleukin-6 levels, sensory-motor disorders, daily physical activity, psychological function and oxidative status in patients with acute ischemic stroke

Protocol summary

Study aim

the effects of coenzyme Q10 on oxidative, inflammatory, brain growth factors, psychological and motor stress indices in patients with acute ischemic stroke

Design

The study is a clinical trial that is double-blind. 50 patients are selected and divided into two groups of 25 patients; The control group receiving placebo; Patients are placed in both groups according to age, gender and severity of stroke so that the two groups are mostly the same. Patients and medical staff will be blinded and only the evaluating researcher is aware of the patient classification.

Settings and conduct

In this study, stroke patients who have been admitted to the neurology ward of Besat Hospital in Hamadan are invited to the study. They begin their healing process. In the intervention group, each patient received 600 mg of coenzyme Q10 daily in the form of 200 mg capsules for 30 days. In the control group, they begin their treatment with placebo capsules that are similar in appearance to the therapy group. Patients and treatment staff will not be aware of the type of capsules.

Participants/Inclusion and exclusion criteria

Patients admitted for acute ischemic stroke can participate in this study; Patients with other neurodegenerative disorders, acute mental disorders, liver or kidney malignancies, rheumatism, and chronic infections, as well as patients who have taken vitamin supplement in the past month; wont be accepted in this study.

Intervention groups

In this study, patients are divided into two groups; The first group of patients receive therapeutic intervention (coenzyme Q10 capsules) and the other group receives placebo capsules.

Main outcome variables

Serum levels of BDNF, interleukin-6; Oxidative indicators include total oxidative capacity, total thiol capacity, malondialdehyde and superoxide dismutase are biochemical variables; Sensory-motor and psychological functions, daily physical activities.

General information

Reason for update

Acronym

CO Q10

IRCT registration information

IRCT registration number: **IRCT20210907052400N1**
Registration date: **2021-09-15, 1400/06/24**
Registration timing: **prospective**

Last update: **2021-09-15, 1400/06/24**
Update count: **0**

Registration date

2021-09-15, 1400/06/24

Registrant information

Name

Siamak Shahidi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3822 2104

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-12, 1400/07/20

Expected recruitment end date

2022-07-21, 1401/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of coenzyme Q10 on brain growth factor and interleukin-6 levels, sensory-motor disorders, daily physical activity, psychological function and oxidative status in patients with acute ischemic stroke

Public title

Evaluation of the effects of coenzyme Q10 on stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute ischemic stroke Patients who have had a stroke for the first time Patients between the ages of 20 and 80

Exclusion criteria:

Having other neurodegenerative disorders Having acute mental disorders Having liver and kidney malignancies Having rheumatism and chronic infections Taking vitamin supplements and immune boosters in the last month

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, a neurologist selects ischemic stroke patients according to inclusion and non-inclusion criteria and introduces them to researchers. After fully explaining the treatment process of this study to patients and obtaining written consent, the researchers enter the patients into the study. After conducting initial assessments, the evaluating researcher provides the physician and nurses with therapeutic intervention, including capsules containing CO Q10 powder and placebo capsules (containing glucose powder), to be placed in the patient's order. The capsules are exactly the same in appearance and packaging, and the medical staff will not be aware of their main contents. The leader researcher in this study is blind and only researchers evaluating and analyzing the data will be aware of the patient classification

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan university of medical sciences, Shahid Fahmideh Blvd, Hamadan

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Hamadan

Postal code

6517838678

Approval date

2021-09-04, 1400/06/13

Ethics committee reference number

IR.UMSHA.REC.1400.444

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Oxidative stress

Timepoint

Immediately after the stroke event and before starting coenzyme Q10 treatment and then 30 days after consuming oral coenzyme Q10

Method of measurement

Spectroscopy (by taking a blood sample)

2

Description

Serum level of interlukin-6

Timepoint
Immediately after the stroke event and before starting coenzyme Q10 treatment and then 30 days after consuming oral coenzyme Q10
Method of measurement
ELISA technique

3

Description
Serum level of Brain Derived Neurotrophic factor
Timepoint
Immediately after the stroke event and before starting coenzyme Q10 treatment and then 30 days after consuming oral coenzyme Q10
Method of measurement
ELISA technique

4

Description
Sensory-motor function
Timepoint
Immediately after the stroke event and before starting coenzyme Q10 treatment and then 30 days after consuming oral coenzyme Q10
Method of measurement
By using Berg Balance Scale

5

Description
Psycho-cognitive function
Timepoint
Immediately after the stroke event and before starting coenzyme Q10 treatment and then 30 days after consuming oral coenzyme Q10
Method of measurement
Using the MoCA questionnaire

6

Description
Physical activity rate
Timepoint
Immediately after the stroke event and before starting coenzyme Q10 treatment and then 30 days after consuming oral coenzyme Q10
Method of measurement
Using SIMPAQ questionnaire and Barthel index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Half of the patients placed in the intervention group by the researcher; After initial evaluation of the initial variables and discharge from the hospital, they begin interventional therapy, which is complementary drug therapy with coenzyme Q10. In this study, patients will consume 600 mg of oral CoQ10 daily in the form of 200 mg capsules (3 servings per day) one hour before the main meals of breakfast, lunch and dinner for 30 days. The coenzyme Q10 oral powder used in this study; It is 98% pure and is made in South Korea.
Category
Treatment - Drugs

2

Description
Control group: The other half of the patients included in the study will be in the control group by the researcher of this study. All evaluations of patients in the intervention group will be performed at the beginning of the study and after discharge from the hospital, as in the first group, they will receive placebo capsules as complementary therapy; Take 3 servings of placebo capsules for 30 days. Patients who are blinded by the type of segmentation and the type of intervention; They receive a 200 mg capsule similar to the intervention capsules. The contents of the capsules of this group are filled with glucose powder
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Be'sat hospaital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Mojtaba Khazaei

Position
Associate professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In this study, only the results related to the study variables will be published

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

All people who are related to scientific and academic centers and industries related to health care can apply.

Under which criteria data/document could be used

Only as a scientific source with the names of the authors are allowed to use the results.

From where data/document is obtainable

Using e-mail addresses, they can contact the researchers of this study and the Vice Chancellor for Research and Technology of the University. Dr. Siamak Shahidi shahidi@umsha.ac.ir Dr. Mojtaba Khazaei khazaeimojtaba@yahoo.com Ali Mojaver. a.mojaver.edu@umsha.ac.ir

What processes are involved for a request to access data/document

Applicants can send an email to the author responsible for the published articles. Request a copy of the article file. To be sent to them by e-mail

Comments