

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of oral administration of ubiquinone in cerebral stroke patients on the neurologic, psycho-cognitive and oxidative stress disorders

Protocol summary

Study aim

the effects of coenzyme Q10 on oxidative, psychological and sensory-motor 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

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

CoQ10

IRCT registration information

IRCT registration number: **IRCT20210907052400N2**

Registration date: **2021-10-06, 1400/07/14**

Registration timing: **prospective**

Last update: **2021-10-06, 1400/07/14**

Update count: **0**

Registration date

2021-10-06, 1400/07/14

Registrant information

Name

Siamak Shahidi

Name of organization / entity

Country

Iran (Islamic Republic of)

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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
Effects of oral administration of ubiquinone in cerebral stroke patients on the neurologic, psycho-cognitive and oxidative stress disorders

Public title
The effects of coenzyme Q10 on cerebral infarction

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
Province
Hamadan
Postal code
6517838678

Approval date
2021-09-04, 1400/06/13

Ethics committee reference number
IR.UMSHA.REC.1400.448

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
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

Using Berg Balance Scale

3

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

4

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

Ali Mojaver

Street address

Be'sat hospital, Shahid Beheshti Blvd, Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

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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

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Latest degree

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Person responsible for updating data

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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,
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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