Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of coenzyme Q10 and placebo on the hearing status of patients with sudden sensorineural hearing loss

Protocol summary

Study aim

Comparison of the effect of coenzyme Q10 and placebo in the treatment of sudden sensorineural hearing loss and hearing-related quality of life

Design

In this double blinded randomized clinical trial with parallel control groups, phase 3, 60 patients with sudden sensorineural hearing loss will be assigned to the intervention and control groups using the envelope method. The intervention group will receive routine treatment plus coenzyme Q10 and the control group will receive routine treatment plus placebo.

Settings and conduct

This study will be performed in Besat Hospital in Hamadan on patients with sudden sensorineural hearing loss. Patients will be randomly allocated into two groups. The intervention group will receive routine treatment plus coenzyme Q10 and the control group will receive routine treatment plus placebo. Both groups will be evaluated for treatment outcome 3 and 6 months later. The study will be double-blind, the outcome assessor and the patient themselves will be unaware of receiving coenzyme Q10 or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria will be Sudden unilateral sensorineural hearing loss according to audiological criteria, age 18 to 70 years and less than one month after the onset of the disease. Conditions of non-entry: History of other ear diseases, the presence of any mass or other pathology in MRI of the ear and conductive hearing loss

Intervention groups

The intervention group, in addition to routine treatment, which includes weekly (for three weeks) injection of dexamethasone into the middle ear, will receive coenzyme Q10 at a dose of 100 mg once daily for 4 weeks. In the control group, routine treatment will be performed similar to the intervention group and they will receive a placebo instead of coenzyme Q10.

Main outcome variables

Main outcome will be changes in hearing status and hearing threshold based on audiograms results.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N23**
Registration date: **2022-05-23, 1401/03/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**
Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

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Name of organization / entity

Hamedan University of Medical Of Science

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of coenzyme Q10 and placebo on the hearing status of patients with sudden sensorineural hearing loss

Public title

The effect of coenzyme Q10 on sudden sensorineural hearing loss treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Unilateral Sudden sensorineural hearing loss Age 18-70 Years Less than one month has passed since the onset of symptoms

Exclusion criteria:

History of other ear diseases Presence of a mass or other pathology on ear MRI Conductive hearing loss

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 cards will be prepared and write letter I on 30 for intervention and on the other 30 letter C for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, randomly select one of the envelopes and open it, based on selected letter (I or C) patients will be allocated it to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be performed double blind, the person who evaluating the outcome of treatment will be unaware of the intervention and control groups. Also participants will be blinded to receiving coenzyme Q10 or placebo according to the same packaging.

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 Science

Street address

Shahid Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838697

Approval date

2022-05-08, 1401/02/18

Ethics committee reference number

IR.UMSHA.REC.1401.135

Health conditions studied

1

Description of health condition studied

sudden sensorineural hearing loss

ICD-10 code

H90.3

ICD-10 code description

Sensorineural hearing loss, bilateral

Primary outcomes

1

Description

Changes in PTA and SRT auditory parameters

Timepoint

3 and 6 months after starting treatment

Method of measurement

Through audiometry and audiogram parameters

Secondary outcomes

1

Description

Hearing-related quality of life

Timepoint

3 and 6 months after starting treatment

Method of measurement

By asking a question: Over the past week, how much has the problem of hearing loss and deafness affected your quality of life in communicating with friends, family and colleagues? And responses on the Likert scale will range from very low to very high.

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Web page address

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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable