Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of co-enzyme Q10 versus placebo on treatment of tinnitus due to presbycusis: a triple-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of co-enzyme Q10 versus placebo on treatment of tinnitus due to presbycusis

Design
This is a triple-blind randomized clinical trial, phase II, in which 50 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients with tinnitus due to presbycusis referring to the Besat Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be triple-blinded so that neither patients nor the physician examining the patients and nor the data analyzer will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 50 to 90 years, Tinnitus for over a year, Bilateral neural sensorineural hearing loss
Exclusion criteria: Psychosomatic disorder, Consumption of calcium, vitamin, and magnesium in the past two months, Tinnitus due to drug side effects, Atypical tinnitus, Meniere's disease, Conductive hearing loss

Intervention groups
Intervention group: Neurotriptyline tablet 25 mg (manufactured by Darupakhsh Pharmaceutical Co.) daily plus co-enzyme Q10 tablet 100 mg (manufactured by Health Aid Co.) daily for 6 weeks Control group: Neurotriptyline tablet 25 mg (manufactured by Darupakhsh Pharmaceutical Co.) daily plus placebo tablet 100 mg daily for 6 weeks

Main outcome variables
Primary outcome: The severity of tinnitus, sleep disorder, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N339**
Registration date: **2020-02-07, 1398/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-07, 1398/11/18**
Update count: **0**

Registration date
2020-02-07, 1398/11/18

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-02-19, 1398/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of co-enzyme Q10 versus placebo on treatment of tinnitus due to presbycusis: a triple-blind randomized

clinical trial

Public title
Effect of co-enzyme Q10 versus placebo on treatment of tinnitus due to presbycusis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 50 to 90 years, Tinnitus for over a year, Bilateral neural sensorineural hearing loss
Exclusion criteria:
Psychosomatic disorder, Consumption of calcium, vitamin and magnesium in the past two months, Tinnitus due to drug side effects, Atypical tinnitus, Meniere's disease, Conductive hearing loss
Age
From **50 years** old to **90 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or
Blinding (investigator's opinion)
Triple blinded
Blinding description
The drugs will be given in coded envelopes. The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions Thus, the trial will be run as triple-blind
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
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2019-07-06, 1398/04/15
Ethics committee reference number
IR.UMSHA.REC.1398.301

Health conditions studied

1

Description of health condition studied
Tinnitus
ICD-10 code
H93.1
ICD-10 code description
Tinnitus

Primary outcomes

1

Description
Severity of tinnitus
Timepoint
Before the intervention and 6 months later
Method of measurement
Using the Tinnitus Handicap Inventory (THI)

2

Description
Sleep disorder
Timepoint
Before the intervention and 6 months later
Method of measurement
Using the Petersburg questionnaire

3

Description
Quality of life
Timepoint
Before the intervention and 6 months later
Method of measurement
Using the SF-36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Neurotriptyline tablet 25 mg (manufactured by Darupakhsh Pharmaceutical Co.) daily plus co-enzyme Q10 tablet 100 mg (manufactured by Health Aid Co.) daily for 6 weeks
Category
Treatment - Drugs

2

Description
Control group: Neurotriptyline tablet 25 mg (manufactured by Darupakhsh Pharmaceutical Co.) daily plus placebo tablet 100 mg daily for 6 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital in Hamadan city
Full name of responsible person
Dr Zahra Sadeghi
Street address
Besat Hospital, Shahed Square
City
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6517838695
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+98 81 3364 0030
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sazcsaz66@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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6517838695
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info.research@umsha.ac.ir
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
Dr Zahra Sadeghi
Position
Resident of ENT
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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Position

Otolaryngologist

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available