Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Acamprosate calcium in tinnitus: a double blind randomized and placebo controlled trial

Protocol summary

Summary

In order to assess drug's efficacy on tinnitus, 30 patients will be included in this controlled double blinded clinical trial study based on their medical status (no contra-indication to prescribing drug) and audiometric level of hearing . They will divide into 2 groups; half will receive 1998 mg/day acamprosate calcium and the other placebo tablets, for 4 weeks. Through validated questionnaires, data such as level of tinnitus annoyance, tinnitus caused disturbance, quality of life, etc will be collected before, mid and after treatment. Pure tone audiometry will be performed twice to confirm its equality. Patients will undergo the oto-acoustic emission tests. These tests will be taken after the end of every treatment schedule. Changes in severity of tinnitus will be assessed through the results of audiometry, changes in OAE results, visual assessment scale (VAS) and loudness match in the end of a one month treatment. Patient will also be asked about the side effects of therapy if any. Analysis would be proceeded after data gathered in excel sheets.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121115751N1**
Registration date: **2015-05-01, 1394/02/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-01, 1394/02/11

Registrant information

Name

Mohammad Mahdi Salem

Name of organization / entity

ENT, Head and neck surgery research center

Country

Iran (Islamic Republic of)

Phone

+98 912 233 5422

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amasghari@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran National Science Foundation ENT, Head and Neck Surgery Research Center, Iran University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-03-05, 1393/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Acamprosate calcium in tinnitus: a double blind randomized and placebo controlled trial

Public title

Acamprosate calcium in tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Normal hearing or mild sensory-neural hearing loss and chronic idiopathic tinnitus(more than 3 months); age between 18 to 65 years/old. exclusion criteria: recent(less than a month) tinnitus treatment including sound or medical therapy; severe co-morbidities like renal, liver or cardiac diseases;

malignancies; past history of treatment-required depression; previous ear surgery; alcohol user; opium or narcotic drugs abuser; pregnant women, lactation.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran university of medical sciences

Street address
Hemmar Highway, before sheikhfazlolah and ghamran highway cross

City
tehran

Postal code

Approval date
2015-01-14, 1393/10/24

Ethics committee reference number
93/105/4942

Health conditions studied

1

Description of health condition studied
Tinnitus

ICD-10 code
H93.1

ICD-10 code description
Tinnitus

Primary outcomes

1

Description
the measure of change in tinitus handicapp inventory

Timepoint
at the end of one month treatment

Method of measurement
audiometry, OAE, VAS, loudness match

Secondary outcomes

empty

Intervention groups

1

Description
Treatment Group with Acamprosate: taking 666mg/every 8 hr for a month (if patient's weight is less than 60 kg, total dose will be half= 333mg/every 8 hr)

Category
Treatment - Drugs

2

Description
treatment group with placebo: taking 2 peals/ every 8hr for one month(if patient is less than 60 kg, total dose will be half=one peal/every 8hr)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram Hospital

Full name of responsible person
Mohammad Mahdi Salem

Street address
ENT, Head and Neck Surgery Research Center, Rasool Akram Hospital, Niayesh str., Sattarkhan str.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran National Science Foundation

Full name of responsible person
Dr. Mohammad Farhadi

Street address
Fifth Alley, Next to Jalal Ale Ahmad Intersection, Northern Karegar Street

City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran National Science Foundation
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
ENT, Head and Neck Surgery Research Center
Full name of responsible person
Dr. Saeid Mahmoudian
Street address
Rasool akram hospital, Niayesh Str., Sattarkhan Str.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
ENT, Head and Neck Surgery Research Center
Proportion provided by this source
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

3

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Mahdi Salem
Street address
Hemmat freeway, next to Milad tower
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
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
ENT, Head and Neck Surgery Research Center
Full name of responsible person
Mohammad Mahdi Salem
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clinical resident
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work

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Web page address

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