Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Carbamazepine and Oxcarbazepine effect on Tinnitus in patients referred to Amir Almomenin Hospital rasht-iran.

Protocol summary

Summary

Tinnitus is a common disorder in general population and affect many age groups. Permanent tinnitus is seen in 6-30% of general population, and 25% of these cases (about 4% general population) tinnitus is very severe that leads to physical and psychological disorders and hampers their quality of life. Recently, the researchers in this field, believe that tinnitus is a seizure type activity in the cortical and sub cortical areas of the brain that leads to aberrant acoustic perception. Therefore anti epileptic agents have been suggested for decrease of tinnitus intensity and relief of the patients from annoying tinnitus. After initial examination the tinnitus subjects by otolaryngologist, the patients will be recruited into the study. Audiometry and tinnitus tests will be performed and then, the patients explain their tinnitus intensity by use of VAS. Also the tinnitus severity index (TSI) questionnaire will be completed for them. After explaining the prossess of the trial, written informed consent will be obtained from participants. Then they will be divided into three groups randomely: for the first group; carbamazepine, for the second group; oxcarbazepine; and for the third group placebo will be administered for 3 months (12 weeks). At the end of 8th and 12th weeks of study tinnitus intensity will be evaluate by VSA criteria and tinnitus quality and patient quality of life will be re-evaluated using TSI questionnaire. Then the results of intervention in three groups will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903061138N2**
Registration date: **2010-05-27, 1389/03/06**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2010-05-27, 1389/03/06

Registrant information

Name
Fataneh Bakhshi
Name of organization / entity
Guilan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical sciences, Vice chancellor for Research

Expected recruitment start date

2010-08-21, 1389/05/30

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Carbamazepine and Oxcarbazepine effect on Tinnitus in patients referred to Amir Almomenin Hospital rasht-iran.

Public title

Effect of Carbamazepine and Oxcarbazepine on Tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-tinnitus history more than 6 months; 2- The patients 21-65 years with nonpulsatile tinnitus. Exclusion crateria:1-pulsatile tinnitus 2-mineare's disease 3-vestibular neurinoma 4-otosclerosis 5-the patients use of hearing-aid 6-pregnancy 7- patients with psychologic disorders need to treatment 8-the nontulerance minimal dose of carbamazepine and oxcarbazepine or hypersensitivity to these drugs 9-recent treatment with anti convulsion drugs 10-OCP consumptions and the drugs interaction with carbamazepine but are necessary to patients 10-patients with severe heart disease(CHF,IHD) 11- appearance severe drug hypersensitivity reaction during of treatment

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **57**

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

Guilan University of Medical Sciences

Street address

Amiralmomenin Hospital

City

Rasht

Postal code

41439

Approval date

2010-05-22, 1389/03/01

Ethics committee reference number

1023/132/پ

Health conditions studied

1

Description of health condition studied

nonpulsatile tinnitus

ICD-10 code

H83

ICD-10 code description

Other diseases of inner ear

Primary outcomes

1

Description

Tinnitus severity

Timepoint

The beginning of treatment and ending of 8th and 12th week

Method of measurement

VAS & TSI

2

Description

Quality of Life

Timepoint

The beginning of treatment and ending of 8th and 12th week

Method of measurement

TSI

Secondary outcomes

empty

Intervention groups

1

Description

Group A(carbamazepine): week 1 = tab 200 mg/daily week 2 -week 12= tab 600 mg/daily (300 mg/ BD)

Category

Treatment - Drugs

2

Description

Group b(oxcarbazepine): week 1= 300 mg/daily then week2- week12 = 900 mg/ daily (450 mg BID)

Category

Treatment - Drugs

3

Description

Group C: intervention with placebo

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasht Amiralmomenin Hospital
Full name of responsible person
Dr Houshang Gerami
Street address
Amiralmomenin Hospital, 17 Shahrivar Ave.
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Vice Chancellor for research
Street address
Amiralmomenin Hospital, Namjou street, Rasht, Guilan, Iran
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan University of Medical Sciences
Proportion provided by this source
100
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
Guilan University of Medical Sciences
Full name of responsible person
Dr Houshang Gerami
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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