Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of alprazolam effect on tinnitus

Protocol summary

Summary

This research is planned to study effectiveness of Alprazolam on non-pulsative tinnitus in patients referred to Amiralmomenin Hospital. 30 patients who have non-pulsative tinnitus for more than 1 year and have not anxiety or depressive disorders will be recruited. At the first, patients are given Chlordiazepoxide (5 mg bid for 14 days). Then eligible patients, who have good cooperation, are selected. After signing informed consent, these patients will be randomized into two groups. In one group Alprazolam (starts with 0.5 mg and increases to 1.5 mg) and in other group active placebo will be given. After 8 weeks, drugs will taper and discontinue completely in 6 days. After 2 weeks washout span, drugs will continue for 8 weeks as cross-over. Primary outcome in this study is severity of tinnitus (through Visual Analog Scale and Tinnitus Handicap Inventory) and tinnitus test (including Loudness matching). Primary outcome will be measured before and during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138709121483N1**
Registration date: **2009-01-01, 1387/10/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-01-01, 1387/10/12

Registrant information

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Mir Mohammad Jalali
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

Pro-vice chancellor, Guilan University of Medical Sciences and Health Services

Expected recruitment start date

2006-11-21, 1385/08/30

Expected recruitment end date

2008-04-19, 1387/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of alprazolam effect on tinnitus

Public title

Evaluation of alprazolam effect on tinnitus in the patients of Rasht Amiralmomenin Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Duration of tinnitus more than 1 year 2- Non pulsative tinnitus Exclusion criteria:1- pulsative tinnitus 2- Meniere's disease 3- Vestibular Schwannoma 4-Otosclerosis 5-Hearing aid users 6- Temporal lobe tumor 7-Depression 8-Anxiety 9- Unable to tolerate minimal effective dose (0.5 mg Alprazolam bid)

Age

From **21 years** old to **65 years** old

Gender

Both

Phase
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)
Triple blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Guilan University of Medical Sciences
Street address
Namjoo street- Rasht
City
Rasht
Postal code
Approval date
2006-08-19, 1385/05/28
Ethics committee reference number
3758/132/3/پ

Health conditions studied

1

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

Primary outcomes

1

Description
tinnitus severity
Timepoint
at -3, 0, 8, 10, 18th week
Method of measurement
Tinnitus Handicap Inventory questionnaire

2

Description
tinnitus test
Timepoint
at -3, 0, 8, 10, 18th week
Method of measurement
loudness matching

3

Description
Severity of Tinnitus
Timepoint
at -3, 0, 8, 10, 18th week
Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Alprazolam 0.5 mg daily for 2 weeks, then 0.5 mg bid for 2 weeks, then 0.5 mg tid for 4 weeks, then 0.5 mg bid for 3 days, then 0.5 mg daily for 3 days
Category
Treatment - Drugs

2

Description
Chlorpheniramine 0.5 mg daily for 2 weeks, then 0.5 mg bid for 2 weeks, then 0.5 mg tid for 4 weeks, then 0.5 mg bid for 3 days, then 0.5 mg daily for 3 days
Category
empty

3

Description
Chlordiazepoxide 5 mg bid for 14 days before initiating the main interventions.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Dr Mir Mohammad Jalali
Street address
17 Sharivar street, Melli Bank sq
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Dr abdolrasol Sobhani
Street address
Mellat St., Namjoo Ave.
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 Sapideh Hajforosh
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Otolaryngology resident
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Person responsible for scientific inquiries

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Person responsible for updating data

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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