

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Name

Mir Mohammad Jalali

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1324 3085

Email address

mmjalali@gums.ac.ir

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

Position

Otolaryngology resident

Other areas of specialty/work

Street address

Amiralmomenin hospital, 17 Sharivar street, Melli

Bank sq

City

Rasht

Postal code

Phone

+98 13 1223 8307

Fax

Email

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Mir Mohammad Jalali

Position

Assistant professor

Other areas of specialty/work

Street address

Amiralmomenin hospital,17 Sharivar street, Melli

Bank sq

City

Rasht

Postal code

Phone

+98 13 1223 8307

Fax

+98 13 1324 1842

Email

mmjalali@gums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Mir Mohammad Jalali

Position

Assistant Professor

Other areas of specialty/work

Street address

Amiralmomenin hospital,17 Sharivar street, Melli

Bank sq

City

Rasht

Postal code

Phone

+98 13 1223 8307

Fax

+98 13 1324 1842

Email

mmjalali@gums.ac.ir

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