

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of ondansetron in patients with tinnitus: double blind control clinical trial

Protocol summary

Summary

This is a randomized double blind clinical trial. Eligible patients are ones with chief complaint of tinnitus without conductive hearing loss who referred to Amiralam hospital. Patients with severe illnesses and psychiatric diseases who need psychiatrist visit are excluded from the study. Patients are randomized into two groups. Intervention group receive ondansetron and control group receive placebo with the same characteristics of main drug. This is a primary study for evaluating the effect of ondansetron on the symptoms of patients with tinnitus. Hence, we try to recruit patients with less restrictions to find subgroups who respond well to ondansetron. Sample size would be based on the time of the study. Primary outcomes are the scores of VAS, THI and TS and secondary outcomes are anxiety and depression scores based on HADS questionnaire and audio metric characteristics and pitch match and loudness match of the tinnitus.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105185867N4**

Registration date: **2011-07-16, 1390/04/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-16, 1390/04/25

Registrant information

Name

Haydeh Samiee

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1857

Email address

hsamiee@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-05-18, 1390/02/28

Expected recruitment end date

2011-11-20, 1390/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of ondansetron in patients with tinnitus:
double blind control clinical trial

Public title

Ondansetron for tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria are: 1) Patients with at least 6 month of tinnitus 2) 18 to 65 year old patients 3) Patients with chief complaint of tinnitus 4) Patients with sensorineural or normal hearing
Exclusion criteria: 1) Patients with severe illnesses and end stage diseases including liver, kidney and heart impairments. Patients with severe psychosis, dementia, cancers and those who are pregnant or lactating. 2) Patients with excessive problems and ones with psychiatric problems needing psychiatrist visit or ones who had an important surgery

recently. 3) Patients with pulsatile tinnitus 4) Patients with worsening of tinnitus with head and neck movements 5) Patients on tinnitus treatment (including sound therapy, complements, drug...) unless still have tinnitus and have been remained on fix dosage of drug for more than acceptable time of action (for medications about 4 weeks). 6) Patients with cerumen impaction (unless tinnitus remained after cerumen removal)

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Tehran University of Medical Sciences Ethics committee

Street address

Tehran University of Medical Sciences central building, Qods street, Keshavarz Blv.

City

Tehran

Postal code

Approval date

2010-06-26, 1389/04/05

Ethics committee reference number

1045-48-01-89

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 loudness based on VAS

Timepoint

At the beginnig and after 4 week

Method of measurement

Questionnaire with 0 to 10 score

2

Description

Tinnitus handicapp scale(THI)

Timepoint

At the beginning and after 4 weeks

Method of measurement

Questionnaire

3

Description

Tinnitus severity

Timepoint

At the beginnig and after 4 weeks

Method of measurement

Questionnaire (Tinnitus severity index questionnaire)

Secondary outcomes

1

Description

SDS

Timepoint

At the begining and after 4 weeks

Method of measurement

Audiometry

2

Description

Depression and anxiety

Timepoint

At the beginning and after 4 weeks

Method of measurement

HADS qestionnaire

3

Description

Side effect

Timepoint

At the beginnig and after 4 weeks

Method of measurement

Questionnaire

4

Description

Tinnitus loudness match

Timepoint

At the beginning and after 4 weeks

Method of measurement

Audiometry

5

Description

Tinnitus pitch match

Timepoint

At the beginning and after 4 weeks

Method of measurement

Audiometry

6

Description

PTA

Timepoint

At the beginning and after 4 weeks

Method of measurement

Audiometry

7

Description

SRT

Timepoint

At the beginning and after 4 weeks

Method of measurement

Audiometry

Intervention groups

1

Description

Ondansetron 16mg for one month (4 tablets a day)

Category

Treatment - Drugs

2

Description

Placebo (4 tablet a day) for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralam hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Private clinic

Full name of responsible person

masoud motesady zarandy

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotuhi

Street address

6th floor, university central organization,qods street,
keshavarz BLv

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shervin Taslimi

Position

MD-MPH

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Person responsible for updating data

Contact

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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