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 compliant 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 group. 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 patient 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 compliant 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
Quesionnaire with 0 to 10 score

2

Description
Tinnitus handicapp scale(THI)

Timepoint
At the beginning and after 4 weeks

Method of measurement
Quesionnaire

3

Description
Tinnitus severity

Timepoint
At the beginnig and after 4 weeks

Method of measurement
Quesionnaire (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 quesionnaire

3

Description
Side effect

Timepoint
At the beginnig and after 4 weeks

Method of measurement
Quesionnaire

4

Description
Tinnitus loudness match
Timepoint
At the beginnig and after 4 weeks
Method of measurement
Audiometry

5

Description
Tinnitus pich match
Timepoint
At the beginnig and after 4 weeks
Method of measurement
Audiometry

6

Description
PTA
Timepoint
At the beginnig and after 4 weeks
Method of measurement
Audiometry

7

Description
SRT
Timepoint
At the begining and after 4 weeks
Method of measurement
Audiomtry

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
Other areas of specialty/work
Street address
ENT ward,Amiralam hospital, sadi street, Tehran
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+98 912 387 0602
Fax

Email
taslimi@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

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Person responsible for updating data

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Email
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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