

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Riluzole on Tinnitus in Patients Referring to Amir Alam Hospital during 2017-18: A randomized, placebo-controlled clinical trial

Protocol summary

Study aim

Investigation of the effect of Riluzole on tinnitus severity

Design

This project is a double-blind randomized controlled clinical trial which is conducted in 2017-18. The study population consisted of all patients aged 18-70 years old, with the chief complaint of tinnitus for more than 3 months who referred to the Tinnitus Clinic of Amiralam Hospital. A total of 48 patients are randomly divided into two equal groups of placebo and main drug group.

Randomization will be done by using the four block size.

Settings and conduct

Patients referred to Tinnitus Clinic of Amiralam Hospital who are eligible for this study are randomly divided into two groups of main drug and placebo. The main drug group will be received the 50 mg Riluzole oral tablet twice a day for three months and the placebo group received a similar drug as a placebo. The tinnitus insensitivity will be assessed with THI questionnaire on the first day and 90th day of the study. Also, in terms of drug side effects, tinnitus pitch match, tinnitus loudness match and maskability are also checked in the same way. The patients and the main investigators who measure the initial outcome are blind to the type of medication.

Participants/Inclusion and exclusion criteria

Patients aged 18-70 years who referred to the Tinnitus Clinic with chief complaint of Tinnitus more than three months are included in the study. Those who had middle and external ear disease; conductive and mixed hearing loss; the presence of the Pulsatile tinnitus type; the presence of temporomandibular joint disorders; receiving medications with Systemic effects (in relation to tinnitus) over the past 6 months; tinnitus with less than three months; mild tinnitus with a THI of > 36 and liver and kidney failure will not be included in the study.

Intervention groups

Intervention includes the administration of oral tablets of Riluzole in one group and the administration of placebo tablets in the control group.

Main outcome variables

The severity of tinnitus was measured by using the THI questionnaire and auditory evaluation using the PTA test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100126003181N2**

Registration date: **2017-11-24, 1396/09/03**

Registration timing: **prospective**

Last update: **2017-11-24, 1396/09/03**

Update count: **0**

Registration date

2017-11-24, 1396/09/03

Registrant information

Name

Zahra Mokhtari

Name of organization / entity

Otorhinolaryngology research center, Tehran university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Riluzole on Tinnitus in Patients Referring to Amir Alam Hospital during 2017-18: A randomized, placebo-controlled clinical trial

Public title
Study of the effect of Riluzole on tinnitus treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having a chief complaint of tinnitus Aged between 18-70
 Tinnitus More than 3 months
Exclusion criteria:
 Middle and external ear disease Patients with conductive and mixed hearing loss The presence of the Pulsatile tinnitus type The presence of temporomandibular joint disorders Receiving medications with Systemic effects (in relation to tinnitus) over the past 6 months The presence of tinnitus with a period Less than three months Mild tinnitus (about THI <36) Patients with liver and renal failure

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by 4 block size.

Blinding (investigator's opinion)
Double blinded

Blinding description
Since the placebo is exactly the same as the original medicine, and when informed consent is informed, the patient is randomly assigned to one of the drug or placebo groups, so the patient is not aware of the type of medication. Also, the main investigator who examined the initial outcome will be blind to patient's drug type, because the allocation is done by another researcher.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Vice Chancellor for research, Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd

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Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-11-12, 1396/08/21

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3956

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Pure tone audiometry

Timepoint

The first day and the 90th day of study

Method of measurement

PTA test

2

Description

Tinnitus severity

Timepoint

The first day and the 90th day of study

Method of measurement

THI (tinnitus handicap inventory) questionnaire

Secondary outcomes

1

Description

tinnitus pitch match

Timepoint

The first day and the 90th day of study

Method of measurement

An assessment by an audiologist

2

Description

Drug side effect

Timepoint

fourth week

Method of measurement

ask from patient

3

Description

maskability

Timepoint

The first day and the 90th day of study

Method of measurement

An assessment by an audiologist

4

Description

tinnitus loudness match

Timepoint

The first day and the 90th day of study

Method of measurement

An assessment by an audiologist

Intervention groups

1

Description

Intervention group: Riluzole 50 mg oral tablet twice daily for three months

Category

Treatment - Drugs

2

Description

Control group: Placebo (similar to the original drug) oral twice daily for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

AmirAlam hospital

Full name of responsible person

Dr. Zahra Mokhtari

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North Saadi Ave.Amiralam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research,Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for research,Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zahra Mokhtari

Position

PhD of Medical Physiology

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable