

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The clinical trial of comparing the effect of fluvoxamine with placebo on intensity of tinnitus due to sensorineural hearing loss

Protocol summary

Summary

(1) Objective: Determination of fluvoxamine effect on tone, frequency and intensity of tinnitus due to sensorineural hearing loss in referred patients to Khorramabad Shohadaye Ashayer Hospital. (2) Design: Randomized / Triple blind / Controlled with Placebo / Single center. (3) Method: Sampling method is based on inclusion criteria. One hundred patients will be randomly divided into two groups of fifty patient, A and B. In group A, fluvoxamine (50 mg daily) and in group B, placebo will be given for one month. Characteristics of tinnitus include frequency, intensity and tone, will be evaluated by tinnitus matching, before and after treatment. Result will be compared at the end of the study. (4) Participants, Inclusion and exclusion criteria: Sample volume is 100. Inclusion criteria: The patients who suffer from sensorineural hearing loss and tinnitus / No contraindication to fluvoxamine / With a written consent form. Exclusion criteria: Using similar drugs / Using other medications that interact with fluvoxamine / Fluvoxamine side effects presentation. (5) Interventions: Fluvoxamine and placebo (capsules consisted of corn starch) will be given to patients for one month. (6) Primary outcome measure: Intensity of tinnitus according to tinnitus matching

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101811157N1**

Registration date: **2012-11-25, 1391/09/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-25, 1391/09/05

Registrant information

Name

Fateme Beiranvand

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 6616200155169

Email address

drkazemi@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The clinical trial of comparing the effect of fluvoxamine with placebo on intensity of tinnitus due to sensorineural hearing loss

Public title

Evaluation of fluvoxamine effect on tinnitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients who suffer from sensorineural hearing loss and tinnitus / No contraindication to fluvoxamine /With a written consent

form Exclusion criteria: Using similar drugs / Using other medications that interact with fluvoxamine / Fluvoxamine side effects presentation

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
This study is triple blind because: (1) Researcher and statistician do not know which one of two drugs the patient has received. (2) The patient does not know which one of two drugs has received. (3) The clinic receptionist gives drugs to patients in pockets marked with A and B. Randomization method: The patients will be matched by stratified block method according to intensity of tinnitus, sex and age groups, and also will be randomly allocated into tow groups, A and B.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Pardis (Kamalvand) Academic Centre, Fifth kilometer of Khorramabad- Brujerd road

City

Khorramabad

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

200/73/740

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes

1

Description

Intensity of tinnitus

Timepoint

Before and one month after intervention

Method of measurement

According to Tinnitus Matching

Secondary outcomes

1

Description

Frequency of tinnitus

Timepoint

Before and one month after intervention

Method of measurement

According to Tinnitus Matching

2

Description

Sex

Timepoint

Before intervention

Method of measurement

According to questionnaire

3

Description

Tone of tinnitus

Timepoint

Before and one month after intervention

Method of measurement

According to Tinnitus Matching

4

Description

Age

Timepoint

Before intervention

Method of measurement

According to questionnaire

5

Description

The satisfaction of treatment

Timepoint

After intervention
Method of measurement
According to Visual Analog Scale

Intervention groups

1

Description

Intervention/ Control1: Fluvoxamine group: Fluvoxamine / Oral Tablet 50 mg / Once a day for one month / Sobhan Company

Category

Treatment - Drugs

2

Description

Intervention/Control2: Control group: Placebo capsule consisted of corn starch / 250 mg / Oral / Once a day for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorramabad Shohadaye Ashayer Hospital

Full name of responsible person

Dr. Siroos Kazemi, Otolaryngologist, Assistant Professor

Street address

Shohadaye Ashayer Hospital, Enghelab Street

City

Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Dr. Mohammad Hasan Kayedi

Street address

Pardis (Kamalvand) Academic Centre, Fifth kilometer of Khorramabad - Brujerd Road

City

Khorramabad

Grant name

124409

Grant code / Reference number

1193

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

Yes

Title of funding source

Lorestan University of Medical Sciences, Vice chancellor for research

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

Lorestan University of Medical Sciences

Full name of responsible person

Dr. Siroos Kazemi

Position

Otolaryngologist, Assistant Professor

Other areas of specialty/work

Street address

Pardis (Kamalvand) Academic Centre, Fifth kilometer of Khorramabad - Brujerd Road

City

Khorramabad

Postal code

Phone

+98 6616200155169

Fax

Email

Drkazemi@lums.ac.ir

Web page address

www.lums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Dr. Siroos Kazemi

Position

Otolaryngologist, Assistant Professor

Other areas of specialty/work

Street address

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Contact

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Fax**Email**

Drkazemi@lums.ac.ir

Web page address

www.lums.ac.ir

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