

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Herbal Formulation (Salvia hydrangea, Citrus aurantium, Lipiacitriodora, and elmbark) on the Amount and Intensity of Tinnitus, randomized clinical trial

Protocol summary

Summary

(1) Aim: finding the scientific evidence to comparison effect of herbal formulation 'Salvia hydrangea, Citrus aurantium, Lipiacitriodora, and elmbark' with Cinnarizine on amount and severity of tinnitus. (2) Design: this single-blind clinical trial of patients visiting the ear clinic with tinnitus problem more than 4 months, enrolled after physical examination, laboratory diagnosis, biochemistry and cell counting and audiogram definitive diagnosis mind tinnitus (pure tone). (3) Methods: the sample randomly divided into three groups: intervention with herbal formulation, intervention and treatment with placebo tablets and Cinnarizine. Before entering the study, forty people besides, during and after the intervention were evaluated clinically. Universal criteria and standards as well as those by the VAS and THI were evaluated. (4) Participant: all patients that visiting ear clinic with inclusion and exclusion criteria and past at least 4 month their tinnitus problem. (5) Interventions: after randomized, patients divided into 3 groups: group A (get Cinnarizine), group B (get herbal formulation) and group C (get placebo). All patients receive their treatment. The placebo in this study was Amidon that place in gelatin capsule. Dosage and mode of administration was educated. All people assessment before, 28 days and 56 days after the schedule has been developed and complete the VAS and THI with physical examination. (6) Main outcome measures variables: tinnitus

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082814505N1**

Registration date: **2015-07-07, 1394/04/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-07, 1394/04/16

Registrant information

Name

Mansour Soltani

Name of organization / entity

Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Herbal Formulation (Salvia hydrangea, Citrus aurantium, Lipiacitriodora, and elmbark) on the Amount and Intensity of Tinnitus, randomized clinical trial

Public title

The Effect of Herbal Formulation (Salvia hydrangea, Citrus aurantium, Lipiacitriodora, and elmbark) on the Amount and Intensity of Tinnitus, randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: giving consent to participate in the study, having an age of 17-70 years old, and suffering from tinnitus for more than 4 months. Exclusion criteria: otitis media, ear tumor, deformity within the ear; ototoxic drugs like gentamicin; ear surgery, pregnancy, breastfeeding or taking birth control pills, extensive surgery or blood transfusion during the previous month, kidney failure, history of stroke or thyroid disease, Otosclerosis, addiction to drugs or alcohol; occupational exposure to noise

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Birjand University of Medical Sciences

Street address

Ghafari Avenue, Birjand, South Khorasan, Iran

City

Birjand

Postal code

5717853577

Approval date

2013-12-01, 1392/09/10

Ethics committee reference number

1392-09-10

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H83.3

ICD-10 code description

Noise Effects On Inner Ear

Primary outcomes

1

Description

Tinnitus Severity

Timepoint

Following at first, one month and if it was needed 2 month later

Method of measurement

Physical Examination, Audiometry

Secondary outcomes

1

Description

Failure Criterion of Tinnitus

Timepoint

At First and One Month Later

Method of measurement

THI & VAS Scales

Intervention groups

1

Description

Group A: receiving Cinnarizine, after randomization we gave to patients Cinnarizine tablets of 25 mg (manufactured by Osve Company). If patients who had failed to respond effectively, (THI>30) intervention was extended for another 28 days. Data collection was based on THI and VAS criteria before 28 and 56 days after intervention.

Category

Treatment - Drugs

2

Description

Group B: receiving herbal formulation (Salvia hydrangea, Citrus aurantium, Lipiacitriodora, and Elmbark), , formulation in sealed packages (4 g of each herb and 12 g of elmbark) with a cup and recipe of herbal tea (5 g of powder of the mixed herbs in a cup of boiled water three times a day before each meal). Data collection was based on THI and VAS criteria before 28 and 56 days after intervention.

Category

Treatment - Drugs

3

Description

placebo in the form of gelatin capsules containing starch was prescribed for 28 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

ENT Clinic, Valiasr Hospital

Full name of responsible person

Dr. Mohhamadreza Mofateh

Street address

Ghafari Avenue, Birjand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Asghar Zarban

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Birjand University of Medical Sciences, Ghafari Avenue, Birjand, South Khorasan, Iran

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Paramedic Faculty

Full name of responsible person

Mansour Soltani

Position

MSC in Nursing

Other areas of specialty/work

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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