Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of silybum marianum in the treatment of tinnitus, a double blind randomized study

Protocol summary

Study aim
Tinnitus treatment with silymarin
Design
Parallel group, double blind, randomised controlled clinical trial
Settings and conduct
This study is designed as a parallel group, double blind, randomised controlled trial. Patients with tinnitus (sample size: 40 patients) who admitted in AmirAlam Hospital in Tehran, and passed inclusion criteria, can participate in this study. Before, in the middle of and at the end of intervention questionnaire will be recorded and analyzed at the end of the study. Patients and physician are blinded about the intervention which will receive.
Participants/Inclusion and exclusion criteria
Inclusion criteria: All of 18-65 years old men and women patients with idiopathic tinnitus Exclusion criteria:1.patients who are pregnant or lactating women, 2. patients with a history of allergy to silymarin, 3.unwilling to complete the study.
Intervention groups
Intervention group: 20 patients (men and women) with idiopathic tinnitus who will receive Livergol(R) 140 mg tablet 3 times a day for three months. Control group: 20 patients (men and women) with idiopathic tinnitus who will receive placebo tablet 3 times a day for three months.
Main outcome variables
Tinnitus status

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160813029327N13**
Registration date: **2018-07-10, 1397/04/19**
Registration timing: **registered_while_recruiting**
Last update: **2018-07-10, 1397/04/19**
Update count: **0**
Registration date
2018-07-10, 1397/04/19

Registrant information
Name
Ramin Abrishami
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-05-22, 1397/03/01
Expected recruitment end date
2018-10-23, 1397/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of silybum marianum in the treatment of tinnitus, a double blind randomized study

Public title
The effect of silybum marianum in the treatment of tinnitus
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with idiopathic tinnitus aged 18-65 years old

Exclusion criteria:

Pregnant and lacatating women History of allergy to silymarin Unwilling to complete the study

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table: based on Random Sequence Generator via random.org website two groups were made. Patients were allocated in one of two groups based on their entry sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind study in which both researcher and patients don't know that which drug the patient have been used. Drugs will be dispensed by a third person in uniform packages with codes. Instructions on the number of consumption will not be seen by the prescriber.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Islamic Azad University of Pharmaceutical Sciences

Street address

#99,The First of Yakhchal Ave., Gholhak, Shariati St.

City

Tehran

Province

Tehran

Postal code

19395-6466

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

IR.IAU.PS.REC.1396.149

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 status

Timepoint

Before the intervention, 6 and 12 weeks after the beginning of the intervention

Method of measurement

Iowa Tinnitus Primary Function Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in people with inclusion criteria to be given 140mg oral silymarin tablet (Livergol (R), Gol Daru), 3 times daily, for three months.

Category

Treatment - Drugs

2

Description

Control group: in people with inclusion criteria to be given oral placebo tablet three times daily for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

AmirAlam Hospital

Full name of responsible person

Mozhgan Safaeyan

Street address

Sa'di Ave.,Enghelab st.,

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
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
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University
Full name of responsible person
Ramin Abrishami
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Position
student
Latest degree
A Level or less
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

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

Data Dictionary

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

Title and more details about the data/document

Patients' Demographic Data, Scores of the Tinnitus primary Function Questionnaire

When the data will become available and for how long

After publication of paper, for one year

To whom data/document is available

Academic persons

Under which criteria data/document could be used

User should cite the primary document

From where data/document is obtainable

Via email to corresponding author

What processes are involved for a request to access data/document

Sending email to corresponding author

Comments