

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 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

###### Name of organization / entity

Islamic Azad University, Pharamceutical sciences branch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2264 1889

###### Email address

r\_abrishami@iaups.ac.ir

##### 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 lactating 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.,

##### City

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Farshad Hashemian  
**Street address**  
Yakhchal St, Shariati st.  
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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  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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Mozhgan Safaeyan  
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**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**