Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of nanocurcumin in the treatment of tinnitus

Protocol summary

Study aim
Tinnitus treatment with nanocurcumin
Design
Pragmatic, community based, parallel group, double blind, randomised controlled trial
Settings and conduct
This study is designed as a parallel group, double blind, randomised controlled trial. The patients with tinnitus (sample size: 60 patients) who admitted to AmirAlam Hospital in Tehran, who have inclusion criteria, will included in this study. Written informed consent from patients is mandatory for entering to the study. In this study patients and physician are blinded. Drugs are labelled with similar labels by a third person with unique identification codes for future identification.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with unknown cause tinnitus Exclusion criteria: Patients with history of head and neck surgery, pregnant or lactating women, history of turmeric allergy, having gallstones or biliary obstruction
Intervention groups
Thirty patients will receive nanocurcumin softgel capsule once daily for three months; and another 30 patients will receive placebo softgel capsules once daily for three months.
Main outcome variables
treatment of tinnitus

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160813029327N15**
Registration date: **2018-07-25, 1397/05/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-25, 1397/05/03**
Update count: **0**
Registration date
2018-07-25, 1397/05/03

Registrant information
Name
Ramin Abrishami
Name of organization / entity
Islamic Azad University, Pharamceutical sciences branch
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-05-21, 1397/02/31
Expected recruitment end date
2019-05-21, 1398/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of nanocurcumin in the treatment of tinnitus

Public title
The effect of Nanocurcumin in Tinnitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All of the patients with unknown cause tinnitus
Exclusion criteria:
History of head and neck surgery Pregnant or lactating women History of turmeric sensitivity Gallstones or

biliary obstruction

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

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 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.1396.148

Health conditions studied

1

Description of health condition studied

Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus, bilateral

Primary outcomes

1

Description

Tinnitus Status

Timepoint

Before treatment, 4 and 12 weeks after treatment

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 80mg oral Nanocurcumin softgel capsule, 4 times daily, for three month.

Category

Treatment - Drugs

2

Description

Control group: in people with inclusion criteria to be given oral placebo capsule one time daily for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir A'lam Hospital

Full name of responsible person

Sahar Hasani

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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
sahar Hasani

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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
Medical Pharmacy

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Person responsible for updating data

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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
To 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