

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of The Effect of Nanocurcumin on Treatment of Tinnitus:A Triple Blinded Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of the effect of Nanocurcumin Supplement in Treatment of Tinnitus

Design

Clinical Trial with Control Group, With Parallel Groups, Triple Blind, Randomized

Settings and conduct

This Study will be Performed with Randomized Controlled Trial among 62 patient with Tinnitus that refer to Besat Hospital in Hamadan . The following will be performed for Audiometric patients including Pure Tone, Speech Perception Threshold, Speech Dissociation Criterion, and Tinnitus Matching Test to assess Tinnitus frequency and loudness. With Impedance Testing will assess Middle ear bone disorders, as well as serous fluid or infection, and Middle ear muscle reflexes. Patients will then be randomly divided into two groups receiving Nano Curcumin and Placebo and the intervention will be performed. After intervention, Tinnitus Conformity Test Questionnaire will be performed and changes recorded and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Unilateral or Bilateral Subjective Tinnitus; 18-65 Year; Patients do not have Pregnancy and Breastfeeding; Patients do not have Acute or Chronic Ear Infection; Patients do not have Rheumatologic Diseases, Vasculitis, Acoustic Neuroma, Known Neurological Disorders and Ear Surgery; Patients not taking Immunosuppressants such as Interferons, Corticosteroids, Anticonvulsants and Sedatives before starting the study Exclusion Criteria is Failure to Cooperate patients

Intervention groups

The Intervention group will Consume Sina 80 mg Nano Nuncumin Supplement with Meals for 21 days . The Control group will consume one Placebo daily for 21 days.

Main outcome variables

Tinitus loudness, Tinnitus Pitch, Tinnitus Handicap

Inventory, Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190916044785N1**

Registration date: **2019-10-20, 1398/07/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-20, 1398/07/28**

Update count: **0**

Registration date

2019-10-20, 1398/07/28

Registrant information

Name

Farhad Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3264 0021

Email address

dr_f_farahani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Used
Scientific title Evaluation of The Effect of Nanocurcumin on Treatment of Tinnitus:A Triple Blinded Randomized Clinical Trial	Assignment Parallel
Public title Evaluation of The Effect of Nanocurcumin on Treatment of Tinnitus	Other design features
Purpose Treatment	Secondary Ids empty
Inclusion/Exclusion criteria Inclusion criteria: Unilateral or Bilateral Subjective Tinnitus Age Range: 18-65 Year Patients do not have Pregnancy and Breastfeeding Patients do not have Acute or Chronic Ear Infection Patients do not have Rheumatologic Diseases, Vasculitis, Acoustic Neuroma, Known Neurological Disorders and Ear Surgery Patients not taking Immunosuppressants such as Interferons, Corticosteroids, Anticonvulsants and Sedatives before starting the study Exclusion criteria: Patients who do not willing to enter the study	Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Hamadan University of Medical Science Street address Research and Technology Vice Chancellor, Hamadan University of Medical Sciences, In front of Mardom Park, Hamadan City Hamadan Province Hamadan Postal code 6517838678
Age From 18 years old to 65 years old	Approval date 2019-09-14, 1398/06/23
Gender Both	Ethics committee reference number IR.UMSHA.REC.1398.467
Phase 3	
Groups that have been masked • Participant • Care provider • Data analyser	Health conditions studied 1 Description of health condition studied tinnitus ICD-10 code H93.1 ICD-10 code description Tinnitus
Sample size Target sample size: 62	Primary outcomes 1 Description Tinnitus Handicap Inventory Timepoint Before and after 21 days of Medicine Consumption Method of measurement Tinnitus Matching Test
Randomization (investigator's opinion) Randomized	Secondary outcomes empty
Randomization description We will write two letter A sheets and two letter B sheets. Mix the sheets together. We will place one in the drawer of the table. Each eligible patient will be randomly pulled out and given A or B drawn. It should be noted that these extruded sheets will not be returned to the drawer until all four sheets have been extracted. In the four sheets, all the sheets are returned to the drawer and the same procedure will continue for the next four patients until the desired sample size is reached	Intervention groups
Blinding (investigator's opinion) Triple blinded	
Blinding description Drugs are excluded from the drug cover and given to the patient without the name of the drug in the envelopes containing Addicts A and B. Therefore, the patient will not be informed of the type of drug used. Therefore, the examining physician will not be aware of the type of drug used by the patients. The intervention and comparison groups will be coded and the data analyst will not be informed of the intervention type. Thus, the study will be conducted in a triple blind manner	
Placebo	

1

Description

The Intervention group will Consume Sina 80 mg Nano curcumin Supplement with Meals for 21 days .

Category

Treatment - Drugs

2

Description

Control group: The Control group will consume Placebo capsul once a day for 21 days. Capsuls are desigend in the same shape with curcumin.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Farhad Farahani

Street address

Next to ENT Clinic, Besat Hospital, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6514845471

Phone

+98 81 3264 0021

Email

dr_f_farahani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Research and Technology Vice-Chancellor, Hamadan University of Medical Sciences, In Front of Mardom Park, Hamadan

City

Hamadan

Province

Hamadan

Postal code

6517838678

Phone

+98 81 3838 0717

Fax

+98 81 3838 0130

Email

bashirian@umsha.ac.ir

Web page address

<http://www.umsha.ac.ir/index.aspx?siteid=135&pageid=15681>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Farahani

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Next to ENT Clinic, Besat Hospital, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6514845471

Phone

+98 81 3264 0021

Email

Zfarahani93@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Farhad Farahani

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Next to ENT Clinic, Besat Hospital, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6514845471

Phone

+98 81 3264 0021

Fax**Email**

dr_f_farahani@yahoo.com

Phone

+98 81 3264 0021

Email

Zfarahani93@gmail.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The Information in the Article will be shared

When the data will become available and for how long

After preparing the Article

To whom data/document is available

Researchers

Under which criteria data/document could be used

Be request

From where data/document is obtainable

The request should be sent to the following Email:

dr_f_farahani@yahoo.com

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

The request should be sent to the following Email:

dr_f_farahani@yahoo.com

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Farahani

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Next to ENT Clinic, Besat Hospital, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6514845471