Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Nurcumin 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

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

Public title
Evaluation of The Effect of Nanocurcumin on Treatment of Tinnitus

Purpose
Treatment

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

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
We will write two letter Asheets 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

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
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

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

Approval date
2019-09-14, 1398/06/23

Ethics committee reference number
IR.UMSHA.REC.1398.467

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 Handicap Inventory

Timepoint
Before and after 21 days of Medicine Consumption

Method of measurement
Tinitus Matching Test

Secondary outcomes

empty

Intervention groups

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@ymail.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

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
Phone
+98 81 3264 0021
Email
Zfarahani93@ymail.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