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
Tinnitus loudness, Tinnitus Pitch, Tinnitus Handicap

Inventory, Side effects

General information

Reason for update

Acronym
IRCT

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
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 analyst

Sample size
- Target sample size: 62

Randomization (investigator's opinion)
- Randomized

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.

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
- Tinnitus 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
6517836678

Phone
+98 81 3838 0717

Fax
+98 81 3838 0130

Email
bashirian@umsha.ac.ir

Web page address

Grant name
Hamedan University of Medical Sciences

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