# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effect of Chinese Ginseng on tinnitus

## Protocol summary

**Study aim**
The effect of Chinese Ginseng on tinnitus
**Design**
Clinical trials without a control group and not blinded
**Settings and conduct**
74 patients with a tinnitus complaint who referred to the Clinic of the Ear and Nose of the Khatam Al-Nabia Hospital used 50 mg of Genikobylbao extract three times a day for 12 weeks. The evaluation of tinnitus and treatment was done by questionnaire. Initially, the researcher gave participants 4 forms of information to provide them the necessary explanations. They were asked to fill out the questionnaires before beginning of the treatment, after 4 weeks of treatment, after 12 weeks of receiving the treatment.
**Participants/Inclusion and exclusion criteria**
Inclusion: Satisfaction with receiving treatment, tinnitus for more than 6 months without any specific cause
Exclusion: Age younger than 18 years of age over 70 years, pregnancy or intent to become pregnant, previous Bilbao extract consumption, tinnitus less than 6 months
**Intervention groups**
The intervention group included patients with tinnitus. First, they were evaluated for anatomic and clinical findings. If there was a clear structural-clinical defect or exit criteria, the patient was excluded. Patients who were included in the study took 50 mg of Genikobylbao extract 3 times a day for 12 weeks.
**Main outcome variables**
Tenitus score

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20180425039418N6**
Registration date: **2019-06-09, 1398/03/19**
Registration timing: **registered_while_recruiting**
Last update: **2019-06-09, 1398/03/19**
Update count: **0**
**Registration date**
2019-06-09, 1398/03/19

**Registrant information**
**Name**
mohammad Ghena'at Pisheh Sanani
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2018-10-17, 1397/07/25
**Expected recruitment end date**
2019-07-16, 1398/04/25
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of Chinese Ginseng on tinnitus

**Public title**
Effect of Chinese Ginseng on tinnitus
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Satisfaction with receiving treatment tinnitus for more than 6 months without any specific cause
**Exclusion criteria:**

Patients under the age of 18 and over 70 years Patients with a specific cause of tenetius

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

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **75**

**Randomization (investigator's opinion)**
N/A

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Ethics committee of Zahedan University of medical sciences

**Street address**
Medical Sciences Campus, Doctor Hesabi Square

**City**
Zahedan

**Province**
Sistan-va-Balouchestan

**Postal code**
9816743463

**Approval date**
2019-09-29, 1398/07/07

**Ethics committee reference number**
IR.ZAUMS.REC.1398.077

## 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 score

**Timepoint**
Before treatment, after 4 weeks of treatment, after 12 weeks of treatment, and finally 4 weeks after treatment

**Method of measurement**
questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Use 50 mg of Genikobylbao extract 3 times a day for 12 weeks.

**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Khatam Al Anbia Hospital

**Full name of responsible person**
Dr Reza Gharibi

**Street address**
Amir Al Momenin street

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Zahedan University of Medical Sciences

**Full name of responsible person**
Dr Reza Gharibi

**Street address**
Dr.Hesabi Square , campus of medical sciences

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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**
Zahedan 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**
Zahedan University of Medical Sciences
**Full name of responsible person**
Dr Reza Gharibi
**Position**
Assistant professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Ear, Nose, and Throat
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be 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 |