Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The Efficacy of bitter almond oil on the severity of chronic tinnitus

Protocol summary

Study aim
To determine the effect of bitter almond oil on the severity of Chronic tinnitus
Design
A controlled clinical trial with blocked randomization phase 3 on 70 patients
Settings and conduct
This study is a controlled clinical trial . In this study, 70 patients aged 17 to 75 years with a diagnosis of tinnitus referred to Amir Alam Hospital, after applying the conditions of entry and exit from the study and completing the informed consent form with random blocking are placed in one of the intervention and control groups.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with chronic tinnitus with doctor confirmation 17 to 75 years old male and female have tendency for entering into study. Exclusion criteria: Pregnancy & breast-feeding, brain surgery, cancer ,Meniere's syndrome ,Pulsatile tinnitus , ear surgery, temporomandibular joint disorders, eardrum rupture, severe vocal trauma, chronic middle and outer ear infection.
Intervention groups
Intervention group: two drops of bitter almond oil every 12 hours + cinnarizine 25 mg tablet every 12 hours for one month Control group: cinnarizine 25 mg tablet every 12 hours for one month
Main outcome variables
The severity of tinnitus

General information

Reason for update
Due to the lack of a placebo, blinding is not done and was removed in the title.
Acronym
IRCT registration information
IRCT registration number: **IRCT20201115049394N1**
Registration date: **2021-02-16, 1399/11/28**
Registration timing: **prospective**

Last update: **2021-03-01, 1399/12/11**
Update count: **1**
Registration date
2021-02-16, 1399/11/28

Registrant information
Name
Maryam Arabi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2249 7446
Email address
m.arabi@mazums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-03-05, 1399/12/15
Expected recruitment end date
2021-08-11, 1400/05/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Efficacy of bitter almond oil on the severity of chronic tinnitus

Public title
The effect of bitter almond oil on the severity of tinnitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Patients with chronic tinnitus with doctor confirmation 17 to 75 years old Male and female Have tendency for entering into study

Exclusion criteria:

Pregnancy & breast-feeding Brain surgery Cancer Meniere's syndrome Pulsatile tinnitus Ear surgery Temporomandibular joint disorders Eardrum rupture Severe vocal trauma chronic middle and outer ear infection

Age

From **17 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table: based on Random Sequence Generator via random.org website, two intervention and control groups were created. Patients were allocated in one of two groups based on their entry sequence.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mazandaran University of Medical Sciences

Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Teacher Street, Teacher's Square

City

Sari

Province

Mazandaran

Postal code

48168-95474

Approval date

2020-10-11, 1399/07/20

Ethics committee reference number

IR.MAZUMS.REC.1399.749

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 severity

Timepoint

Before the intervention and ending of 2th and 4th week

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

disability of tinnitus

Timepoint

Before the intervention, 2 and 4 weeks after the beginning of the intervention

Method of measurement

Tinnitus Handicap Inventory (THI) for participants with tinnitus disorder

Intervention groups

1

Description

Intervention group:: receiving Bitter Almond ear drops with the licence of Medical Equipment Department by Barig Essence Company, two times a day, each time 2 drops and 25 mg Cinnarizine tablet two times a day for one months.

Category

Treatment - Drugs

2

Description

Control group: receiving orally 25 mg Cinnarizine tablet two times a day, for one months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir Alam Hospital
Full name of responsible person
Dr Assie Jokar
Street address
Amir Alam Hospital
City
Tehran
Province
Tehran
Postal code
6511111457
Phone
+98 21 6634 3352
Fax
+98 21 6670 6106
Email
hamiralam@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Majid Saidi
Street address
Deputy of Research and Technology Mazandaran University of Medical Sciences, Moalem Ave., Moalem Square
City
Sari
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Phone
+98 11 3325 7230
Email
pajhooheshi@mazums.ac.ir
Web page address
https://pajooheshi.mazums.ac.ir/page-NPajooheshiMain/fa/2/form/pId47946ردیف
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
70
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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Assie Jokar
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Center for Traditional Medicine and Complementary Medicine of mazandaran university; Khazar Boulevard, Khazar Square of Sari
City
Sari
Province
Mazandaran
Postal code
48168-95475
Phone
+98 11 3324 4893
Email
a.jokar@mazums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Assie Jokar
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Center for Traditional Medicine and Complementary Medicine of mazandaran university; Khazar Boulevard, Khazar Square of Sari
City
Sari
Province
Mazandaran
Postal code
48168-95475
Phone
+98 11 3324 3117
Email
a.jokar@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Maryam Arabi
Position
Persian Medicine Student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Center for Traditional Medicine and Complementary Medicine of mazandaran university; Khazar Boulevard, Khazar Square of Sari
City
Sari
Province
Mazandaran
Postal code
48168-95475
Phone
+98 11 3324 3117
Email
m.arabi@mazums.ac.i

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