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

**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**
recruiting

**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
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
1793375184

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
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