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
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

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
hamiram@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
۱۷۹۳۳۷۵۱۸۴
Phone
+98 11 3325 7230
Email
pajhooheshi@mazums.ac.ir
Web page address
https://pajooheshi.mazums.ac.ir/page-NPajooheshiMai
n/fa/2/form/pld47946ردﯾﻒ

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
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
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