

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Dec 2023

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

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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

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Amir Alam Hospital

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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

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Other areas of specialty/work

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Web page address<https://pajhooeshi.mazums.ac.ir/page-NPajhooeshiMain/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****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

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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