

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Evaluation of the effect of Nigella sativa consumption on improving the symptoms of Meniere's disease in Meniere's patients

Protocol summary

Study aim

Determining the effect of Nigella sativa consumption on the improvement of tinnitus in meniere's patients
Determining the effect of Nigella sativa consumption on improvement of hearing loss in meniere's patients
Determining the effect of Nigella sativa consumption on improvement of dizziness in meniere's patients

Design

Study contains 2 groups of intervention and control. A total of 40 meniere's patients included in the study. This sample size is calculated by STATA software. Patients are divided into two groups by balanced block randomization method with two arms by STATA software. The study is a phase 3 parallel group single-side blind clinical trial with control group

Settings and conduct

Patients are selected from 2 centers of Amir alam hospital and Dr. Masoud Motasadi ear clinic. They enter the study with single side blind method so that only patients are blinded to the study. The study period is 3 months in which patients in addition to previous basic treatment, receive placebo in control group and Nigella sativa in intervention group

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who are definite cases of meniere's disease
Exclusion criteria: history of cardiac, hepatic, renal, psychiatric and hypertension diseases

Intervention groups

Patients in intervention group receive 1 capsule containing 1 gram of Nigella sativa oil daily and in control group receive 1 capsule daily containing 1 gram of placebo orally for 3 months. Patients before entering the study, received half a tablet of Triamterene H 50/25 daily and tablet of Betahistine 16 twice a day. In this study, this previous basic treatment is continued in 2 groups

Main outcome variables

Hearing loss improvement
Tinnitus improvement
Dizziness improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201102049238N1**

Registration date: **2021-01-13, 1399/10/24**

Registration timing: **prospective**

Last update: **2021-01-13, 1399/10/24**

Update count: **0**

Registration date

2021-01-13, 1399/10/24

Registrant information

Name

Zahra Rabbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8601 3261

Email address

z-rabbani@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-06, 1400/01/17

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Nigella sativa consumption on improving the symptoms of Meniere's disease in Meniere's patients

Public title

The effect of Nigella sativa on Meniere's disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are definite cases of Meniere's disease

Exclusion criteria:

History of cardiac disease History of hepatic disease

History of renal disease History of psychiatric disease

History of hypertension disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

In order to maintain the balance and equality of the number of people in the study groups, and to prevent the imbalance of the groups, the balanced block randomization method will be used. For this purpose, 10 blocks of four will be considered (n=40) so that in each block, two people will belong to the intervention group and two people will belong to the control group. In each block, the order in which people are assigned to each group will be random, and this process will be repeated for all blocks. So we have 6 possible combinations including AABB, BABA, BAAB, ABAB, ABBA, BBAA (Group A represents the intervention group and group B represents the control group). Finally, based on the available combinations, the letters A and B, which indicate intervention or control, will be written inside the closed envelopes and the number of each patient will be written on the envelopes (The first patient, the second patient, the third patient, and up to the fortieth patient, respectively). An envelope is then opened for each patient who is recruited to determine which group the patient should be assigned to. The randomization process will be performed using STATA16 statistical software.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blind study, only participants (patients) are blinded. They know that by entering this study, they will be divided into two groups: placebo and medicine, but they do not know in which group they will be placed. But members of the research group such as the principal investigator, analyst, etc. are aware of the distribution of participants into two groups of drug and placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Research of Amir Alam Hospital Complex

Street address

North Saadi St., Enghelab St.

City

Tehran

Province

Tehran

Postal code

6611111457

Approval date

2021-01-04, 1399/10/15

Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1399.041

Health conditions studied**1****Description of health condition studied**

Meniere's disease

ICD-10 code

H81.09

ICD-10 code description

Meniere's disease, unspecified ear

Primary outcomes**1****Description**

Improvement of tinnitus

Timepoint

At the beginning of the study and 3 months after starting the consumption of Nigella sativa

Method of measurement

Tinnitus Handicap Inventory questionnaire

2**Description**

Improvement of hearing loss

Timepoint

At the beginning of the study and 3 months after starting the consumption of Nigella sativa

Method of measurement

Audiometry

3

Description

Improvement of vertigo

Timepoint

At the beginning of the study and 3 months after starting the consumption of Nigella sativa

Method of measurement

Dizziness Handicap Inventory questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: capsules containing 1 gram of Nigella sativa oil, oral consumption, 1 gram per day for 3 months, Barij Essence company+ continuation of the previous basic treatment of patients including triamterene H 50/25 (half a tablet daily) and betahistine 16 (twice a day)

Category

Treatment - Drugs

2

Description

Control group: capsules containing 1 gram of placebo, oral consumption, 1 gram per day for 3 months, Barij Essence company+ continuation of the previous basic treatment of patients including triamterene H 50/25 (half a tablet daily) and betahistine 16 (twice a day)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Masoud Motasadi Ear Clinic

Full name of responsible person

Dr. Masoud Motasadi Zarandy

Street address

No 26, 3rd alley, Vozara St.

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2

Recruitment center

Name of recruitment center

Amir Alam hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Motasadi Zarandy

Street address

Tehran University of Medical Sciences, Poursina Avenue, Qods Street, Enqelab Square

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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

Tehran 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

Motasaddi@yahoo.com

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Rabbani

Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Motasadi Zarandi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Rabbani

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

Ear, Nose, and Throat

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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