Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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 parellel 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.
City
Tehran
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1513634111
Phone
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2

Recruitment center
Name of recruitment center
Amir Alam hospital
Full name of responsible person
Dr. Masoud Motasadi Zarandy
Street address
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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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1417613151
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motasaddi@yahoo.com
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

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

Contact

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Full name of responsible person
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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