Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of vitamin D supplementation in reducing vertigo attacks and severity in Meniere’s patients, A Randomized Double-Blind Clinical Trial with Placebo-Controlled

Protocol summary

Study aim
Evaluation of the effect of vitamin D supplementation in reducing vertigo attacks and severity in Meniere’s patients

Design
Randomized Double-Blind Clinical Trial With Placebo-Controlled

Settings and conduct
In Amir Alam Hospital. At beginning and end of the intervention (after 8 weeks of consuming vitamin D), each patient completes questionnaires (Dizziness Disability Questionnaire, Visual Analogue Scale, Tinnitus Disability Questionnaire) in which questions about severity, repetition and duration of vertigo attacks and the severity of tinnitus and their impact on the patient's quality of life. Serum levels of 25 (OH) vitD3 are also measured at these two times. A person other than researcher codes vitamin D supplement and placebo package based on a list of random numbers to ensure that researcher and participants are not informed.

Participants/Inclusion and exclusion criteria
1) Patients >18 with a definitive diagnosis of MD whose serum level of 25 (OH) vitD3 is less than 30 and more than 10 ng / ml. 4) In cases of taking drugs affect absorption and metabolism of vitamin D, having neurological or autological disorders or otitis media or chronic metabolic disorders affecting the level of vitamin D such as malabsorption and. .. or severe hepatic failure, renal failure, uncontrolled hypothyroidism, primary hyperparathyroidism, cystic fibrosis, pregnant or breastfeeding, excluded from the study.

Intervention groups
For people in the drug group, in addition to receiving the usual Meniere treatment (betahistine), Pearl Vitamin D supplement 50,000 units, one per week, after lunch and for 8 weeks will be prescribed, and in the second group, placebo, which is quite similar to vitamin D supplement in terms of Shape and color are considered, given.

Main outcome variables
determining the effect of vitamin D supplementation in reducing vertigo attacks and severity in Meniere’s patients

General information

Reason for update
The clinical trial start date was entered incorrectly due to a typographical error.

Acronym

IRCT registration information
IRCT registration number: **IRCT20210716051908N1**
Registration date: **2021-10-10, 1400/07/18**
Registration timing: **prospective**

Last update: **2023-10-15, 1402/07/23**
Update count: **1**

Registration date
2021-10-10, 1400/07/18

Registrant information

Name
ali talebi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8840 3503

Email address
talebi-a@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-06, 1400/08/15

Expected recruitment end date
2022-10-22, 1401/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of vitamin D supplementation in reducing vertigo attacks and severity in Meniere's patients, A Randomized Double-Blind Clinical Trial with Placebo-Controlled

Public title
Evaluation of the effect of vitamin D supplementation in reducing vertigo attacks and severity in Meniere's patients, A Randomized Double-Blind Clinical Trial with Placebo-Controlled
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a definitive diagnosis of MD according to the guidelines of the American Academy of Otolaryngology (AAO-HNS) (≥ 2 episodes of spontaneous vertigo, each lasting at least 20 minutes to 12 hours, along with an audiometric test that Indicates sensorineural hearing loss in the ear involved in low frequency and clinical symptoms such as tinnitus, feeling of fullness of the ear) Age over 18 years Serum levels of 25 (OH) vitD3 less than 30 ng / ml and more than 10 ng / ml
Exclusion criteria:
Serum levels of 25 (OH) vitD3 less than 10 ng / ml Consumption of drugs that affect absorption and metabolism of vitamin D (such as: carbamazepine, phenytoin, phenobarbital, rifampin, glucocorticoids, hormonal compounds such as ocp, Bile acid sequestrants, sevelamer, orlistat ...) History of liver disease (chronic liver disease), kidney (chronic renal failure with GFR ˂ 60 ml / min with persistent increase in parathyroid hormone), uncontrolled hypothyroidism, cystic fibrosis, primary hyperparathyroidism History of neurological disorders History of other autologous diseases Patients with otitis media Having chronic metabolic disorders that may affect vitamin D levels (malabsorption, gastrointestinal surgery, celiac disease, inflammatory bowel disease (IBD)). Pregnant, breastfeeding Reluctance to continue the project, at any time and for any reason during the study Serious side effects during treatment
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to one of two groups of vitamin D supplements and placebo based on the permuted block randomization method, which will use 6 blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
A person other than the researcher who does not have information on how to perform and the purpose of the study will use a list of random numbers to encode the vitamin D supplement and placebo and will be numbered according to the list so that the researcher does not know the type of supplements. Participants will also have no information about the contents of the package.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Working Group / Ethics Committee in Research Institute of Pharmaceutical Sciences, Tehran University
Street address
pharmacy facualty, 16 azar street, keshavarz Ave
City
tehran
Province
Tehran
Postal code
1111111111111111
Approval date
2021-09-25, 1400/07/03
Ethics committee reference number
IR.TUMS.TIPS.REC.1400.137

Health conditions studied

1

Description of health condition studied
meniere disease

ICD-10 code
H81.0
ICD-10 code description
Meniere's disease

Primary outcomes

1

Description
1. Comparison of the average severity of dizziness before and after the intervention in the group consuming vitamin D supplements
Timepoint
Beginning of the study (before the intervention) and end of the eighth week (end of the intervention)
Method of measurement
Visual Analogue Scale, Dizziness Handicap Inventory

2

Description
2. Comparison of mean severity of vertigo before and after intervention in the placebo group
Timepoint
Beginning of the study (before the intervention) and end of the eighth week (end of the intervention)
Method of measurement
Visual Analogue Scale, Dizziness Handicap Inventory

3

Description
3. Comparison of mean recurrence of vertigo before and after the intervention in the group consuming vitamin D supplements
Timepoint
Beginning of the study (before the intervention) and end of the eighth week (end of the intervention)
Method of measurement
Number of dizziness attacks per month

4

Description
Comparison of mean recurrence of vertigo before and after intervention in the placebo group
Timepoint
Beginning of the study (before the intervention) and end of the eighth week (end of the intervention)
Method of measurement
Number of dizziness attacks per month

5

Description
Comparison of the mean duration of dizziness before and after the intervention in the group consuming vitamin D supplements
Timepoint
Beginning of the study (before the intervention) and end of the eighth week (end of the intervention)
Method of measurement
The average duration of vertigo attacks per vertigo

6

Description
6. Comparison of the mean duration of vertigo before and after the intervention in the placebo group
Timepoint
Beginning of the study (before the intervention) and end of the eighth week (end of the intervention)
Method of measurement
The average duration of vertigo attacks per vertigo

7

Description
7. Determining the mean frequency × duration of vertigo in the group consuming vitamin D supplement and comparing it with the placebo group
Timepoint
Beginning of the study (before the intervention) and end of the eighth week (end of the intervention)
Method of measurement
The result of daily vertigo in each patient is calculated as the duration of vertigo × the recurrence of vertigo

Secondary outcomes

1

Description
Comparison of the mean severity of tinnitus before and after the intervention in the group taking vitamin D supplements
Timepoint
Beginning of the study (before the intervention) and end of the eighth week (end of the intervention)
Method of measurement
Tinnitus Handicap Inventory

2

Description
Comparison of the mean severity of tinnitus before and after the intervention in the placebo group
Timepoint
Beginning of the study (before the intervention) and end of the eighth week (end of the intervention)
Method of measurement
Tinnitus Handicap Inventory

Intervention groups

1

Description
Intervention group: In addition to receiving the usual Meniere treatment (betahistine) , Pearl Vitamin D supplement 50,000 units, one per week, after lunch and for 8 weeks will be prescribed.
Category
Rehabilitation

2

Description
Control group: The placebo, which is exactly the same as the vitamin D supplement in shape and color, will be delivered once a week, after lunch, for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
ENT Clinic of Amir Alam Hospital
Full name of responsible person
Ali Talebi
Street address
Amir Alam Hospital, North Saadi Ave
City
Tehran
Province
Tehran
Postal code
1145765111
Phone
+98 21 6670 8103
Email
amiralam@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Niayesh Mohebbi
Street address
Poursina Ave, District 6, Tehran University of Medical Science
City
tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8889 6696
Email
tumspr@tums.ac.ir
Web page address
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
Ali Talebi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Poursina Ave, District 6, Tehran University of Medical Sience, pharmacy facualty
City
Tehra
Province
Tehran
Postal code
1417614411
Phone
02164120
Email
alitph8@gmmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Talebi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Poursina Ave, District 6, Tehran University of Medical Sience, Pharmacy Facualty
City
Tehran
Province
Tehran
Postal code
1417614411
Phone

02164120
Email
alitph8@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Talebi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Poursina Ave, District 6, Tehran University of Medical Science, Pharmacy facualty
City
Tehran
Province
Tehran
Postal code
1417614411
Phone
02164120
Email
alitph8@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable