

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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) ( $\geq 2$  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  $\leq$  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 analyst
- 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 faculty, 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 Science, pharmacy faculty

**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 Science, Pharmacy Faculty

**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

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**Street address**

Poursina Ave, District 6, Tehran University of Medical Science, Pharmacy faculty

**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