Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The effect of vitamin D on the cumulative size and number of uterine fibroids in women aged 30-45 years with uterine fibroids and hypovitaminosis D.

Protocol summary

Study aim

To evaluate the effect of vitamin D supplementation on the number and total volume of uterine fibroids in premenopausal women aged 30–45 years with uterine fibroids and vitamin D deficiency.

Design

This study is a randomized, placebo-controlled, parallel-group, double-blind clinical trial. A total of 130 participants will be randomly allocated in a 1:1 ratio to either the vitamin D supplementation group or the placebo group using opaque, sealed envelopes to ensure allocation concealment.

Settings and conduct

This study will be conducted at the gynecology clinics of Imam Hossein Hospital. Eligible women with uterine fibroids and vitamin D deficiency will be randomly assigned to intervention and control groups and followed for 3 months, after which study outcomes will be assessed.

Participants/Inclusion and exclusion criteria

Premenopausal women aged 30–45 years with ultrasonographically confirmed uterine fibroids (total volume 64–512 cm^3) and vitamin D deficiency [25(OH)D <20 ng/mL] will be eligible. Exclusion criteria include malabsorption disorders, chronic kidney disease, severe fibroid-related symptoms requiring immediate treatment, cardiovascular disease, diabetes mellitus, malignancy, and osteomalacia or osteoporosis requiring vitamin D therapy.

Intervention groups

Intervention group: Participants with vitamin D insufficiency (12–20 ng/mL) will receive oral vitamin D 1000 IU daily for 3 months. Participants with vitamin D deficiency (<12 ng/mL) will receive vitamin D 50,000 IU weekly for 6–8 weeks followed by 1000 IU daily until completion of the 3-month intervention period. Control group: Participants will receive a placebo administered according to the same dosing schedule and duration as the intervention group.

Main outcome variables

1. Change in the number and cumulative size of uterine fibroids 2. Serum 25-hydroxyvitamin D [25(OH)D] level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251121068065N6**
Registration date: **2026-06-16, 1405/03/26**
Registration timing: **prospective**

Last update: **2026-06-16, 1405/03/26**
Update count: **0**

Registration date

2026-06-16, 1405/03/26

Registrant information

Name

kavoushgaran kavoushgaran

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

atiye.hesary@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-28, 1405/04/07

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of vitamin D on the cumulative size and number of uterine fibroids in women aged 30-45 years with uterine fibroids and hypovitaminosis D.

Public title
The effect of vitamin D on the cumulative size and number of uterine fibroids in women aged 30-45 years with uterine fibroids and hypovitaminosis D.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 30–45 years who are premenopausal. Presence of uterine fibroids confirmed by abdominal and transvaginal ultrasonography. Total fibroid volume between 64 and 512 cm^3. Serum 25-hydroxyvitamin D [25(OH)D] level <20 ng/mL (vitamin D deficiency or insufficiency). Provision of written informed consent.
Exclusion criteria:
Malabsorption disorders. Chronic kidney disease or renal failure. Severe fibroid-related symptoms requiring immediate treatment (e.g., heavy bleeding causing anemia, severe pelvic pain, or significant urinary tract compression). Cardiovascular disease. Diabetes mellitus. Any malignancy. Osteomalacia or osteoporosis requiring therapeutic vitamin D supplementation. Withdrawal of consent or unwillingness to continue participation.
Age
From **30 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly allocated to the intervention (vitamin D) or control (placebo) group in a 1:1 ratio using a sealed, opaque envelope randomization method. The randomization sequence will be generated by an independent investigator using Microsoft Excel prior to participant enrollment. Group allocation cards will be prepared in equal numbers and placed in sequentially numbered, opaque, sealed envelopes. After enrollment, each participant will be assigned to a study group by selecting one envelope. This procedure will ensure random allocation and concealment of group assignment throughout the enrollment process.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted using a double-blind design. Participants will be unaware of their group allocation (vitamin D or placebo). In addition, the sonographer responsible for ultrasonographic assessments and the experienced midwife involved in participant follow-up and outcome assessment will be blinded to treatment allocation. Therefore, both participants and outcome assessors will remain unaware of group assignment throughout the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of School of Medicine - Shahid Beheshti University of Medical Sciences
Street address
6th Floor, Building No. 2, Shahid Beheshti University of Medical Sciences Headquarters, Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2026-05-19, 1405/02/29
Ethics committee reference number
IR.SBMU.MSP.REC.1405.103

Health conditions studied

1

Description of health condition studied
Leiomyoma of uterus (Uterine fibroids)
ICD-10 code
D25
ICD-10 code description
Leiomyoma of uterus

Primary outcomes

1

Description

Number and cumulative size of uterine fibroids.

Timepoint

The number and cumulative volume of uterine fibroids will be assessed at two time points: baseline (prior to initiation of the intervention) and at the end of the 3-month intervention period (post-intervention).

Method of measurement

Fibroid number and cumulative volume will be assessed by transabdominal ultrasonography (TAS) and transvaginal ultrasonography (TVS) performed by a trained sonographer.

2

Description

Serum 25-hydroxyvitamin D [25(OH)D] level

Timepoint

Serum 25-hydroxyvitamin D levels will be measured at two time points: baseline (before initiation of the intervention) and upon completion of the 3-month intervention period.

Method of measurement

Serum 25-hydroxyvitamin D [25(OH)D] levels will be measured using high-performance liquid chromatography (HPLC) with a Pars Azmoon Chromium assay kit.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Participants will receive a placebo administered according to the same dosing schedule and duration as the intervention group.

Category

Treatment - Drugs

2

Description

Intervention group: Participants with vitamin D insufficiency (12–20 ng/mL) will receive oral vitamin D 1000 IU daily for 3 months. Participants with vitamin D deficiency (<12 ng/mL) will receive vitamin D 50,000 IU weekly for 6–8 weeks followed by 1000 IU daily until completion of the 3-month intervention period.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Clinic of Imam Hussein Hospital

Full name of responsible person

Dr. Noushin Amjadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Noushin Amjadi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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