

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Comparison of vitamin D and placebo supplementation in reducing uterine myoma size in women with vitamin D deficiency

#### Protocol summary

##### Study aim

Determine the effectiveness of vitamin D supplements in reducing uterine myoma size in women with vitamin D deficiency

##### Design

Clinical trials with drug and placebo control group, treatment-based, with parallel groups, blind, randomized by block

##### Settings and conduct

This is a clinical trial study of women with uterine myoma referred to women clinics of Alzahra and Shahid Beheshti Hospitals in Isfahan. Patients are randomly divided into two groups. A group receive vitamin D and a group placebo, that patients are blinded to type of treatment. Six months later, Sonography is done again. The sonographer has also been blinded to type of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients who are willing to participate and consent to participate in the study. 2) In an ultrasound, have 1-2 uterine myoma is 20-80 millimeters 3) The serum level of vitamin D is less than 20 ng / ml  
Exclusion criteria 1) Consuming hormone 2) Severe bleeding

##### Intervention groups

Participants are randomly divided into 2 groups A and B. To group A, vitamin D supplementation is provided from Iran's Zahravi factory with a dose of 50,000 units every 2 weeks for 10 weeks. Group B patients are given a placebo.

##### Main outcome variables

Change the size of the myoma

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160521027998N5**

Registration date: **2018-01-29, 1396/11/09**

Registration timing: **retrospective**

Last update: **2018-01-29, 1396/11/09**

Update count: **0**

##### Registration date

2018-01-29, 1396/11/09

##### Registrant information

###### Name

Maryam Hajihashemi

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3776 6578

###### Email address

m\_hajihashemy@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2015-09-22, 1394/06/31

##### Expected recruitment end date

2016-09-21, 1395/06/31

##### Actual recruitment start date

2015-09-22, 1394/06/31

##### Actual recruitment end date

2016-08-21, 1395/05/31

##### Trial completion date

empty

##### Scientific title

Comparison of vitamin D and placebo supplementation in reducing uterine myoma size in women with vitamin D deficiency

##### Public title

Study of Vitamin D Effect on myoma size

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having 1 to 2 uterine leiomyomas with size 20-80 mm

Serum levels of 25-hydroxyvitamin D3 <20 ngr/ml.

Signed a inform consent form to participate in the study

### Exclusion criteria:

Consuming hormonal drugs Massive vaginal bleeding

## Age

From **35 years** old to **49 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **72**

Actual sample size reached: **69**

## Randomization (investigator's opinion)

Randomized

## Randomization description

all eligible patients before intervention were randomly divided into two groups using a block randomization procedure

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Group A received vitamin D 50,000 IU every 2 weeks for 10 weeks (Iranian Zahravi Corp.), while group B received placebo with same color and shape. Ultrasound was performed for evaluating uterine leiomyomas size with same operator who don't know about intervention and in same previous center 6 months later.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Deputy of Isfahan University of Medical Sciences and Health Services

##### Street address

Hezar Jirib

##### City

ESFAHAN

##### Province

Isfahan

## Postal code

۷۳۴۶۱-۸۱۷۴۶

## Approval date

2015-05-25, 1394/03/04

## Ethics committee reference number

IR.MUI.REC.1394.3.453

## Health conditions studied

### 1

#### Description of health condition studied

Uterine myoma

#### ICD-10 code

D25.9

#### ICD-10 code description

D25.9Leiomyoma of uterus, unspecified

## Primary outcomes

### 1

#### Description

Uterine myoma size

#### Timepoint

Before the intervention begins and 6 months after the intervention begins

#### Method of measurement

X8 medison ultrasound machine

## Secondary outcomes

### 1

#### Description

Serum vitamin D levels

#### Timepoint

Before intervention and 6 months after intervention

#### Method of measurement

Radioimmunoassay

## Intervention groups

### 1

#### Description

Intervention group: received vitamin D 50,000 IU every 2 weeks for 10 weeks (Iranian Zahravi Corp.)

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Received placebo with same color and shape of vit d in intervention group

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
Shahid Beheshti Hospital- Esfahan  
**Full name of responsible person**  
Maryam Ansari  
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### 2

#### Recruitment center

**Name of recruitment center**  
Alzahra Hospital  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
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Dr. Ahmad Movahedian Attar  
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+98 31 3668 8138

#### Email

research@mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Esfahan 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**  
Esfahan University of Medical Sciences  
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Maryam Ansari  
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Resident  
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## Person responsible for scientific inquiries

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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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