

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Effect of vit D supplements on fibroid size in women who have insufficient levels and comparison by control group

#### Protocol summary

##### Summary

The aim of study is to evaluate the effects of vit D supplements on decreasing myoma size, in women who have myoma and insufficient levels of vit D .All eligible patients who have myoma and referred to Yas hospital will be entered to the study. These women need observation or treatment, after they have signed informed consent for participation to study, sonogram will be done for evaluation of the size of myoma then Vit D level is measured and according to the level of vitD ,if the level is deficient so they will be prescribed vit D 50000 weekly for treatment, and they will be excluded from study; if the level is insufficient they will be divided to both groups , one group will receive vit D supplement and the other group will be observed as control group. After 8 weeks myoma size again will be measured by sonogram .The results of the myoma size will be gathered. Randomization is done by a computed generated random numbers program . Patients and physicians are not blinded to study groups but the radiologist and lab technicians are blind regarding study groups. The sample size is 170 patients with myoma for this study. History of infertility, type of myoma, BMI, and age will be gathered and analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201703122576N15**

Registration date: **2017-07-09, 1396/04/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-09, 1396/04/18

#### Registrant information

##### Name

Fatemeh Davari Tanha

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8831 3955

##### Email address

fdavaritanha@sina.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Deputy of research of Tehran University of Medical Sciences

#### Expected recruitment start date

2017-04-01, 1396/01/12

#### Expected recruitment end date

2019-04-01, 1398/01/12

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of vit D supplements on fibroid size in women who have insufficient levels and comparison by control group

#### Public title

Effect of vit D levels on myoma size

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: All women who have myoma and referred to hospital; Level of vit D is insufficient or deficient; age 18-50 years old Exclusion criteria: All women who have myoma and sufficient levels of vitD

**Age**

From **18 years** old to **50 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **170**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomization is done by a computed generated random numbers program by a technician who is not blind to study

**Secondary Ids****1****Registry name****Secondary trial Id****Registration date**

2017-11-21, 1396/08/30

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Fifth floor, Central building of TUMS, Ghods Ave, Keshavarz Boulevard

**City**

Tehran

**Postal code****Approval date**

2016-06-20, 1395/03/31

**Ethics committee reference number**

IR.TUMS.VCR.REC.1396.2701

**Health conditions studied****1****Description of health condition studied**

Myoma

**ICD-10 code**

D-25

**ICD-10 code description**

Myoma

**Primary outcomes****1****Description**

Size of myoma

**Timepoint**

0,8 weeks

**Method of measurement**

Sonogram before starting study and 8 weeks after starting treatment protocol

**Secondary outcomes****1****Description**

Vit D levels

**Timepoint**

Before study ,after 8 weeks

**Method of measurement**

Level of vit D before the study and 8 weeks after starting treatment protocol

**Intervention groups****1****Description**

Intervention group: Pearl vit D 50000 once per week for 8 weeks orally

**Category**

Treatment - Drugs

**2****Description**

Control group: No supplement of Vit D prescribed during 8 weeks

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Yas Hospital

**Full name of responsible person**

Fatemeh Davari Tanha

**Street address**

Karim khan bridge, North Ostad Nejatollahi avenue, Yas Hospital

**City**

Tehran

## Sponsors / Funding sources

**1**

### Sponsor

**Name of organization / entity**

Vice chancellor for research of Tehran University of Medical Sciences

**Full name of responsible person**

Miss Mostofi

**Street address**

Fifth floor, Central building of TUMS, Ghods Ave, Keshavarz Boulevard

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research of Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Davari Tanha

**Position**

Associate Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*