

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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)

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Email address

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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 computer 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

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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