Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Maryam Hajihashemi

Name of organization / entity
Isfahan University of Medical Sciences

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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
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Province
Isfehan
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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
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2

Recruitment center
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Sponsors / Funding sources

1

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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
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
Full name of responsible person
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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