Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of Vitamin D effect in compare to placebo in decreasing of leiomyoma size in patients with uterine leiomyoma

Protocol summary

Summary

Aims: Determining the effect of vitamin D supplementation in the treatment of uterine leiomyoma. Study design: randomized, double-blind, placebo controlled, single center, clinical trial, phase 2-3. Study population: women with uterine leiomyoma if have vitamin D deficiency will be selected as target population. Main inclusion criteria: age between 20 and 45 years, patients with uterine fibroid, which the largest is greater than 3 cm on ultrasound, vitamin D levels less than 75 nmol per liter or 30 ng per milliliter. Main exclusion criteria: myoma with acute symptoms which will require to surgery, liver or kidney disorders, of the uterus, cervix and ovarian cancers, adnexal mass, endometrial lesions, use of hormonal therapy in the last three months, pregnancy and breastfeeding, delivery within the last six months, uterine leiomyoma more than 12 cm, the size of the uterine leiomyoma more than 20 weeks, malabsorption syndrome. Sample Size: 40 patients, 20 as the intervention group and 20 in the control group (B) Interventions: The patients in case group will receive vitamin D (brand name: Vitamin-D 50000IU, manufactured by Zahravi pharmaceutical company, Iran) one pearl per week for eight weeks, after which if the levels of vitamin D was normal, vitamin D continued one pearl per month and if the levels of vitamin D was low vitamin D continued one pearl per week for 4 weeks. Patients in control group will receive placebo (manufactured by Zahravi pharmaceutical company, Iran) in similar route to intervention group. (C) The intervention time: After the evaluation and also 2, 3 and 4 months after the initiation of intervention in any visit the signs bleeding and spotting, pictorial bleeding assessment chart (PBAC) and visual analog scale (VAS) score will be evaluated. Ultrasound will be done in forth month after intervention. (D) The primary outcome: reducing the size of leiomyoma, decreasing of blood loss in patients with leiomyoma, reduce clinical signs criteria caused by Leiomyoma.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121511019N4**
Registration date: **2015-02-24, 1393/12/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-24, 1393/12/05

Registrant information

Name
Mojgan Rahmanian
Name of organization / entity
Semnan University of Medical Sciences
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Iran (Islamic Republic of)
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rahmanian@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Semnan University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment of Vitamin D effect in compare to placebo in decreasing of leiomyoma size in patients with uterine leiomyoma

Public title
Vitamin D or placebo in treatment of uterine leiomyoma

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age between 20 and 45 years, having one or more uterine fibroids, the largest be 3 cm based on ultrasound, vitamin D and 25-hydroxyvitamin D concentrations lower than 75 nmol per liter or 30 ng/ml. Exclusion criteria: Leiomyoma with acute symptoms which requiring to immediate surgical intervention, liver or kidney disorders, cancer of the uterus, cervix and ovarian, adnexal mass, endometrial lesions such as polyps on ultrasound, use of hormonal therapy in the last three months, pregnancy, lactation or the desire to become pregnant during the study period, delivery within the last six months, uterine myoma in size more than 12 cm, the size of the uterine leiomyoma more than 20 weeks, history of gastrointestinal problems, especially malabsorption syndrome.

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Study designed as double-blind clinical trial, so that the investigator and the patient do not know about what they received (drug or placebo). Be the first person in the intervention or the control group specified by tossing up and the rest assigned as every other.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Semnan University of Medical Sciences

Street address
Basidj Boulevard, Semnan University of medical Sciences

City
Semnan

Postal code

Approval date
2014-12-22, 1393/10/01

Ethics committee reference number
2285/2/12/93

Health conditions studied

1

Description of health condition studied
Volume and duration of mensturation, Leiomyoma of uterus, size

ICD-10 code
N92.0, N92

ICD-10 code description
Irregular menstruation, Leiomyoma of uterus, unspecified, Excessive and frequent mensturation with regular or irregular cycle

Primary outcomes

1

Description
Size of Uterine Liomyoma

Timepoint
4 months after intervention

Method of measurement
Sonography study

Secondary outcomes

1

Description
Menstrual bleeding and related symptoms

Timepoint
2, 3 and 4 months after intervention

Method of measurement
Pictorial Blood Loss Assessment Chart (PBAC) and Visual analog scale (VAS)

Intervention groups

1

Description
The patients in case group will receive vitamin D pearl (brand name: Vitin-D 50000IU, manufactured by Zahravi pharmaceutical company, Iran)one per week for eight weeks, after which if the levels of vitamin D was normal, vitamin D continued one pearl per month and if the levels of vitamin D was low vitamin D continued one

pearl per week for 4 weeks.

Category

Treatment - Drugs

2

Description

Patients in control group will receive placebo pearl (manufactured by Zahravi pharmaceutical company, Iran) in similar route to intervention group for 8 weeks and followed without any additional interventions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Momenin Hospital

Full name of responsible person

Dr. Mahboobeh Saghafi

Street address

Imam Hussein Square

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Semnan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Asgari

Street address

Basidj Boulevard

City

Semnan

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 and Technology, Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Dr. Mahboobeh Saghafi

Position

Gynecology resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Semnan University of Medical Sciences

Full name of responsible person

Dr. Mojgan Rahmanian

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Gynecologist/ Assistant professor

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mehrdad Zahmatkesh

Position

Nurse/ Research expert

Other areas of specialty/work

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Kowsar Hospital, Al Ghadir Square, Amin Ave.

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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