

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of vitamin D supplementation on uterine myoma of women attending to hospital

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

A clinical trial study on women with uterine myoma referred to women clinics of Khaleej-e-fars Hospital in Bandar Abbas. Patients are randomly divided into two groups. One group receive vitamin D and the other group will receive placebo. All participants are blinded to type of treatment. 4 months later, Sonography is done again. The sonographer has also been blinded to type of treatment.

Participants/Inclusion and exclusion criteria

Women with uterine myoma with a lack of vitamin D levels who were referred to women clinics of Khaleej-e-fars Hospital in Bandar Abbas

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 week for 12 weeks. Group B patients are given a placebo.

Main outcome variables

Change in the size of the myoma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040046N1**

Registration date: **2018-08-29, 1397/06/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-28, 1398/05/06**

Update count: **1**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Somayye Arzhe

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3362 4314

Email address

dr.arzhe@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on uterine myoma of women attending to hospital

Public title

The effect of vitamin D supplementation on uterine myoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are willing to participate and consent to participate in the study Having 1-3 uterine myoma with at least 10 millimeters diameter in largest myoma according to ultrasound findings Serum level of vitamin D less than 30ng / ml

Exclusion criteria:

Consuming hormone Severe vaginal bleeding Planning for pregnancy

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

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

Blindness will be that the supplementation of vitamin D and placebo will not be communicated to anyone by someone outside the research team and team members such as a clinical care provider, and supplementary participants

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bandar Abbas University of Medical Sciences

Street address

Shahid Mohammadi hospital in Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.HUMS.REC.1397.045

Health conditions studied

1

Description of health condition studied

Uterine myoma

ICD-10 code

D25.9

ICD-10 code description

Leiomyoma of uterus, unspecified D25.9

Primary outcomes

1

Description

Size of uterine myoma

Timepoint

Before intervention and 4 months after intervention

Method of measurement

sonography

Secondary outcomes

1

Description

Serum vitamin D levels

Timepoint

Before intervention and 4 months after intervention

Method of measurement

Radioimmunoassay

Intervention groups

1

Description

Intervention group: received vitamin D 50,000 IU every week for 12 weeks (Iranian Zahravi Corp.)

Category

Treatment - Drugs

2

Description

Control group: received placebo every weeks for 12 weeks (Iranian Zahravi Corp.)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khaleej-e-fars Hospital of Bandar Abbas
Full name of responsible person
Somayye Arzhe
Street address
Pardis Blvd,Persian Gulf Hospital
City
Bandar Abbas
Province
Hormozgan
Postal code
7919783141
Phone
+98 76 3367 0280
Email
dr.arzhe@hums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Maryam Azizi
Street address
saheli Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7916839319
Phone
+98 76 3366 6368
Email
mail@hums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person

Fatemeh Darsareh
Position
Midwife
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Bagh Aonir st. Amir Abad
City
Bandar Abbas
Province
Hormozgan
Postal code
7918796758
Phone
+98 67 3355 4515
Fax
Email
famadarsareh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Somayye Arzhe
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
No.103, Eisar2 Alley, Eisar Ave
City
Bandar Abbas
Province
Hormozgan
Postal code
7915879837
Phone
+98 76 3362 4314
Fax
Email
mohammadsomayye@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Somayye Arzhe
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics

Street address

No.103, Eisar2 Alley, Eisar Ave

City

Bandar Abbas

Province

Hormozgan

Postal code

7915879837

Phone

+98 76 3362 4314

Fax**Email**

mohammadsomayye@gmail.com

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

Yes - There is 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

Title and more details about the data/document

No more information

When the data will become available and for how long

No more information

To whom data/document is available

No more information

Under which criteria data/document could be used

No more information

From where data/document is obtainable

No more information

What processes are involved for a request to access data/document

No more information

Comments