

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of vitamin D on quality of life and symptom severity of symptomatic uterine Leiomyoma in women

Protocol summary

Study aim

1.Comparison of quality of life score and score of uterine leiomyoma symptoms before, 2 and 4 months after intervention in control and intervention groups and also compare the two groups with each other. 2.Comparison of serum levels of 25-hydroxy vitamin D3 before and 4 months after intervention in the intervention and control groups.

Design

A randomized clinical trial which include control group with parallel groups, Triple-blind, Sample size: 92 women, 4-block randomization

Settings and conduct

In this research,the researcher, research samples, and statistical analyst are not aware of the type of drug used for the two groups.Both drugs are provided in same forms and with specific codes by the pharmacist .Research setting will be the women clinic of Baharloo Hospital and the research community will be 92 women. Individuals who met the inclusion criteria put into control or intervention groups by block randomization.They will be treated for 8 weeks and reassessed 2 and 4 months after the intervention.

Participants/Inclusion and exclusion criteria

Age between 15-49 years, At least existence of one confirmed uterine leiomyoma in the ultrasound without requiring of surgery, Existence of uterine leiomyoma symptoms in history,Under medical treatment of uterine leiomyoma, 25 hydroxy vitamin D values less than 30 ng/ml, Absence of pelvic pathology , Absence of contraindication for vitamin D intake, Absence of chronic medical condition, Not being pregnant or Unwilling to become pregnant within the next 6 months and no lactation.

Intervention groups

Intervention group: Medical treatment of uterine leiomyoma with Pearl Vitamin D 50,000 units, weekly for 8 weeks. Control group: Medical treatment of uterine leiomyoma with placebo similar to Pearl Vitamin D,

weekly for 8 weeks.

Main outcome variables

Quality of life score ,Score of uterine leiomyoma symptoms,Serum levels of 25-hydroxy vitamin D3

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160821029446N7**

Registration date: **2020-04-04, 1399/01/16**

Registration timing: **prospective**

Last update: **2020-04-04, 1399/01/16**

Update count: **0**

Registration date

2020-04-04, 1399/01/16

Registrant information

Name

Maryam Damghanian

Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D on quality of life and symptom severity of symptomatic uterine Leiomyoma in women

Public title

The effect of vitamin D on quality of life and symptom severity of symptomatic uterine Leiomyoma in women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 15-49 years At least existence of one confirmed uterine leiomyoma in the ultrasound without need of surgery Existence of uterine leiomyoma symptoms in history Under medical treatment of uterine leiomyoma 25 hydroxy vitamin D values less than 30 ng/ml

Exclusion criteria:

Pathology existence of the uterus, ovaries and adnexes in sonography Existence of contraindication for vitamin D intake Existence of any chronic medical condition Pregnancy or desire to become pregnant within the next 6 months and lactation

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly divided into two groups of intervention and control, so that we first design 4 blocks of different types of probability, so that in each block two of the intervention group and two of the control group will be placed. The number of possibilities in this case will be 6. Then create a list of random numbers between 1 and 6 and arrange the blocks according to the list of numbers obtained until the total number of samples is covered.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a Randomized Controlled Trial, Triple-blind

trial in which the researcher, research sample and statistical analyst are not aware of the type of drug used for the two groups. In this research, both drugs are provided in identical shapes and with specific codes by the Pharmacist and are provided to the research units.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of School of Nursing and Midwifery & Rehabilitation - Tehran University of Medical

Street address

Nursing and Midwifery Faculty of Tehran University of Medical Sciences, Tohid Square, Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2020-02-18, 1398/11/29

Ethics committee reference number

IR.TUMS.FNM.REC.1398.190

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

Uterine leiomyoma

ICD-10 code

D25.9

ICD-10 code description

Leiomyoma of uterus, unspecified

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

Quality of life

Timepoint

Before, 2 and 4 months after intervention

Method of measurement

Uterine Fibroid Symptom & Health-Related Quality Of Life Questionnaire

2

Description

Uterine Fibroid Symptom

Timepoint

Before, 2 and 4 months after intervention

Method of measurement

Uterine Fibroid Symptom & Health-Related Quality Of Life Questionnaire

Secondary outcomes

1

Description

Serum concentration of 25-hydroxy vitamin D3

Timepoint

Before and 4 months after intervention

Method of measurement

Elisa test

Intervention groups

1

Description

Intervention group: will receive 50,000 weekly dose of Pearl Vitamin D in addition to medical treatment of uterine leiomyoma for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: will receive a placebo once a week for 8 weeks, the composition of which will be similar in form and size to Pearl Vitamin D that include water, in addition to medical treatment of uterine leiomyoma.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharloo hospital

Full name of responsible person

Maryam Damghanian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Samira Noorzaie

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available