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

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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
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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
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Full name of responsible person
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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