Effect of vitamin D on the recurrence rate of uterine fibroid

Protocol summary

Study aim
Effect of vitamin D on the recurrence of uterine fibroids in patients referred to Rasoul-e-Akram Hospital in 1396-1397

Design
Before to surgery, vitamin D levels were measured by blood test. After surgery, a trans-vaginal sonography was performed after the first menstruation, and in the case of normal ultrasonography, patients were randomly divided into two groups of 68 patient, the first group received vitamin D, and the second group was patients Which is considered as a control group and does not receive any medication. Each participant will be assigned a code.

Settings and conduct
This study was conducted at the Endometriosis Research Center. Patients who have been hysteroscopy myomectomy surgery have been included in the study. The amount of vitamin D in the study group is as follows: The daily intake of 1000 units of vitamin D is administered orally for 12 months.

Participants/Inclusion and exclusion criteria
inclusion criteria: 1- Uterine Fibroid; 2- hysteroscopy myomectomy 3-vitamin D levels less than the normal range; 4- Informed consent after Explaining the Purpose and Method of Research; 5-Normal transvaginal ultrasonography after the first menstruation after surgery

Intervention groups
The method of administration of vitamin D in the study group is to prescribe orally 1000 units of vitamin D per day for 12 months. There is no intervention in the control group.

Main outcome variables
The outcome of this study is the measurement of recurrence and size of fibroma based on the results of transvaginal sonography.

General information

Reason for update
Expansion of sampling time and revising of some incorrectly entered variables

Acronym
IRCT registration information
IRCT registration number: IRCT2015090923949N3
Registration date: 2017-12-26, 1396/10/05
Registration timing: registered_while_recruiting

Last update: 2020-12-13, 1399/09/23
Update count: 1

Registration date
2017-12-26, 1396/10/05

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-22, 1396/09/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
2017-11-22, 1396/09/01

Actual recruitment end date
2020-07-22, 1399/05/01

Trial completion date
2020-07-22, 1399/05/01

Scientific title
Effect of vitamin D on the recurrence rate of uterine fibroid
Public title
Effect of vitamin D on the recurrence of uterine fibroids

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
- Uterine Fibroid hysteroscopy myomectomy vitamin D
- less than normal range Informed consent after Explaining the Purpose and Method of Research Normal Trans-vaginal ultrasonography after the first menstruation after surgery

Exclusion criteria:
- Age
  - From 30 years old to 45 years old
- Gender
  - Female

Phase
4

Groups that have been masked
No information

Sample size
- Target sample size: 136
- Actual sample size reached: 109

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization in this study is block randomized and four blocks are used. In each block, two of the intervention group and two of the control group are placed. In this study, 10 blocks are selected on a random number table. The entry of individuals to each of the groups will be respectively the number of block choices and the layout in the block.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Used

Assignment
Parallel

Other design features
Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Sattarkhan Street; Mazar-i-Mansouri St; Rasoul-e-Akram Hospital

City
Tehran

Province

Tehran

Postal code
1445613131

Approval date
2017-11-20, 1396/08/29

Ethics committee reference number
IR.IUMS.REC 1396.30623

Health conditions studied

1
Description of health condition studied
Uterine Fibroma

ICD-10 code
D25.0

ICD-10 code description
Submucous leiomyoma of uterus

Primary outcomes

1
Description
recurrence of uterine Fibroid

Timepoint
12 mounts after surgery

Method of measurement
transvaginal ultra sonography

Secondary outcomes
empty

Intervention groups

1
Description
Intervention group: will receive 1000 units of vitamin D - orally - per day for 12 months.

Category
Prevention

2
Description
Control group: no intervention in this group

Category
Prevention

Recruitment centers

1
Recruitment center
Name of recruitment center
Rasoul-e-Akram Hospital

Full name of responsible person
Dr. Mansoureh Vahdat

Street address
Rasoul-e-Akram Hospital, Mazar-i-Mansouri St.,
Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran 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
Iran 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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**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**  
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