

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing between prescription and not prescription of vitamin D on recurrence of endometriosis related pains, after laparoscopic surgery

#### Protocol summary

##### Summary

Goal : Comparison of pain recurrence between prescription and not prescription of vitamin D after laparoscopic surgery in patients with endometriosis. If results of prescription and not prescription of vitamin D on recurrence of endometriotic pains had significant difference, it can be beneficial on treatment of endometriosis. Inclusion criteria : 15-45 years women that during laparoscopy endometriosis is confirmed and in second menstruation after operation the score of pain for dysmenorrhea or pelvic pain will be 3 or more. Exclusion criteria : The women that have received vitamin D in last 6 months, the women that will not continue the follow up. Research population : The women with endometriosis that in second menstruation after operation have pain score 3 or more. Sample size : 11 patients in each group ( total = 22 ) Intervention : Prescription and not prescription of vitamin D In vitamin D group from 2 cycles after operation for 16 weeks will take 50000 IU vitamin D ( Dana Tabriz - Iran ) weekly and in non vitamin D prescription group placebo each week until 16 weeks. Primary results : Pelvic pain and dysmenorrhea between 2 groups will be compared 6 months after operation.

#### General information

##### Acronym

vitamin D and endometriosis

##### IRCT registration information

IRCT registration number: **IRCT2013021912151N3**

Registration date: **2014-09-23, 1393/07/01**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-09-23, 1393/07/01

#### Registrant information

##### Name

Fariba Almassinokiani

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2202 4187

##### Email address

f-almasi@sina.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Minimally invasive surgery research center , Iran University of Medical Sciences

#### Expected recruitment start date

2014-09-01, 1393/06/10

#### Expected recruitment end date

2015-10-02, 1394/07/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing between prescription and not prescription of vitamin D on recurrence of endometriosis related pains, after laparoscopic surgery

#### Public title

Comparing between prescription and not prescription of vitamin D on recurrence of endometriosis related pains

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria : 15-45 years women that during laparoscopy endometriosis is confirmed and in second

menstruation after operation the score of pain for dysmenorrhea or pelvic pain will be 3 or more. Exclusion criteria : The women that have received vitamin D in last 6 months, the women that will not continue the follow up.

#### **Age**

From **15 years** old to **45 years** old

#### **Gender**

Female

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **22**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Iran University of Medical Sciences

##### **Street address**

Tehran,Hemmat pathway

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2014-08-31, 1393/06/09

#### **Ethics committee reference number**

93-02-140-24388-103892

### **Health conditions studied**

#### **1**

#### **Description of health condition studied**

Endometriosis of pelvic peritoneum

#### **ICD-10 code**

N80.3

#### **ICD-10 code description**

Endometriosis of pelvic peritoneum

### **Primary outcomes**

#### **1**

#### **Description**

Severity of dysmenorrhea

#### **Timepoint**

2 cycles after operation

#### **Method of measurement**

VAS test

#### **2**

#### **Description**

Severity of dysmenorrhea

#### **Timepoint**

before operation

#### **Method of measurement**

VAS test

#### **3**

#### **Description**

Severity of dysmenorrhea

#### **Timepoint**

4 months after starting vitamin D

#### **Method of measurement**

VAS test

### **Secondary outcomes**

#### **1**

#### **Description**

dysmenorrhea

#### **Timepoint**

4 months after starting vitamin D

#### **Method of measurement**

VAS test

### **Intervention groups**

#### **1**

#### **Description**

In intervention group oral pearls of vitamin D ( 50000 IU - Dana Tabriz Company-Iran ) per week until 16 weeks after operation will be prescribed.

#### **Category**

Treatment - Drugs

#### **2**

#### **Description**

in control group one oral pearl of placebo ( 50000 IU - Dana Tabriz Company-Iran ) weekly until 16 weeks.

#### **Category**

Placebo

### **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Rasoul-e-Akram Hospital

**Full name of responsible person**

Dr.Fariba Almassi

**Street address**

Iran , Tehran , Sattarkhan street

**City**

Tehran

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Minimally Invasive Surgery Research Center of Iran  
University of Medical Sciences

**Full name of responsible person**

Dr Fariba Almassi

**Street address**

Tehran , Rasoul-e-Akram Hospital

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Minimally Invasive Surgery Research Center of Iran  
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**

Iran University of Medical Sciences ( IUMS )

**Full name of responsible person**

Dr Fariba Almassi

**Position**

Obstetrician and Gynecologist , Fellw ship of  
laparoscopy

**Other areas of specialty/work**

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### Person responsible for scientific inquiries

#### Contact

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Fariba Almassi. MD

**Position**

Associate Professor of Iran University of Medical  
Sciences

**Other areas of specialty/work**

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### Person responsible for updating data

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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*