

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### Evaluation of Lipid Profiles and Plasma Vitamin D Levels in Endometriosis Patients' before and after Radical Laparoscopic Surgery

#### Protocol summary

##### Study aim

Evaluation of Lipid Profiles and Plasma Vitamin D Levels in Endometriosis Patients' before and after Radical Laparoscopic Surgery

##### Design

Clinical trial, before and after, includes 29 patients

##### Settings and conduct

This study is a clinical trial with the participation of all patients with endometriosis who will be referred to Shohada Tajrish Hospital from August 1, 2019 to June 21, 2020 for surgery. Data were collected using a questionnaire including age, BMI, number of pregnancies, abortion, delivery, painful menstruation, pelvic pain, dyspareunia, intermittent spotting, familial history of endometriosis, history of Pelvic infections are contraceptive pills. In order to measure serum lipid profiles and vitamin D levels after 12 hours of fasting, 5 cc of venous blood samples from both groups will be taken before surgery. In patients with endometriosis, two months after surgery, the level of lipid profile and vitamin D will be measured again. Profile lipid contains cholesterol, triglycerides, LDL, and HDL.

##### Participants/Inclusion and exclusion criteria

Entry requirements: endometriosis patients; 15- 45 years old; no pregnancy; laparoscopic Surgery candidate; no drug use, especially OCP, from 3 months before surgery; no drug use, until 2 months after surgery. Exclusion conditions: systemic medical conditions including high blood pressure and diabetes; hypothyroidism & hyperthyroidism; pregnancy; BMI> 30; hyperlipidemia; smoking; drinking.

##### Intervention groups

Endometriosis patients who are candidates for radical laparoscopic surgery

##### Main outcome variables

The level of lipid profiles in endometriosis patients after laparoscopic radical surgery changes (HDL decreases and the rest of the lipid profiles increase); Plasma vitamin D levels increase in patients with endometriosis

after laparoscopic radical surgery.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190529043753N1**

Registration date: **2019-07-25, 1398/05/03**

Registration timing: **prospective**

Last update: **2019-07-25, 1398/05/03**

Update count: **0**

##### Registration date

2019-07-25, 1398/05/03

##### Registrant information

##### Name

Mohadese Alemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7721 0526

##### Email address

alemi\_mohadese@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-01, 1398/05/10

##### Expected recruitment end date

2020-06-20, 1399/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
Evaluation of Lipid Profiles and Plasma Vitamin D Levels in Endometriosis Patients' before and after Radical Laparoscopic Surgery

**Public title**  
Evaluation of Lipid Profiles and Plasma Vitamin D Levels in Endometriosis Patients' before and after Radical Laparoscopic Surgery

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Endometriosis patients 15- 45 years old No pregnancy Laparoscopic Surgery candidate No drug use, especially ocp, from 3 months before surgery No drug use, until 2 months after surgery  
**Exclusion criteria:**  
Systemic medical conditions including high blood pressure and diabetes hypothyroidism & hyperthyroidism pregnancy BMI> 30 Hyperlipidemia smoking Drinking

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

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **29**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**  
**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**  
National Ethics Committee for Biomedical Research  
**Street address**  
Ghods Town (West), Between South Falamak and Zarafshan, Iran-Iran Street - Central Headquarters of the Ministry of Health and Medical Education, block A, thirteenth floor  
**City**

tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۱۹۹۴۳۴۷۱  
**Approval date**  
2019-05-07, 1398/02/17  
**Ethics committee reference number**  
IR.SBMU.MSP.REC.1398.075

## Health conditions studied

### 1

**Description of health condition studied**  
endometriosis  
**ICD-10 code**  
N80  
**ICD-10 code description**  
Endometriosis

## Primary outcomes

### 1

**Description**  
Serum vitamin D levels in people with endometriosis before and after surgery  
**Timepoint**  
Before Surgery and 2 months after surgery  
**Method of measurement**  
Take 5 cc blood sample after 12 hours of fasting and report on ng / ml

### 2

**Description**  
Serum cholesterol levels in people with endometriosis before and after surgery  
**Timepoint**  
Before Surgery and 2 months after surgery  
**Method of measurement**  
Take 5 cc blood sample after 12 hours of fasting and report on mg / dl

### 3

**Description**  
Serum triglyceride levels in people with endometriosis before and after surgery  
**Timepoint**  
Before Surgery and 2 months after surgery  
**Method of measurement**  
Take 5 cc blood sample after 12 hours of fasting and report on mg / dl

### 4

**Description**  
Serum LDL levels in people with endometriosis before and after surgery  
**Timepoint**

Before Surgery and 2 months after surgery  
**Method of measurement**  
Take 5 cc blood sample after 12 hours of fasting and report on mg / dl

## 5

**Description**  
Serum HDL levels in people with endometriosis before and after surgery

**Timepoint**  
Before Surgery and 2 months after surgery

**Method of measurement**  
Take 5 cc blood sample after 12 hours of fasting and report on mg / dl

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

**Description**  
Radical Laparoscopic Surgery

**Category**  
Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

Shohadaye Tajrish Hospital

**Full name of responsible person**

Mohadese Alemi

**Street address**

shohadaye tajrish hospital, shahrdari st.Tajrish Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2274 9201

**Email**

Pr\_shohada@sbmu.ac.ir

**Web page address**

<http://shmc.sbmu.ac.ir/index.jsp?siteid=90>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zarghi Afshin

**Street address**

Shahid Beheshti University of Medical Sciences,  
Yemen street, Shahid Araj St., Shahid Chamran  
highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2243 9781

**Email**

zarghi@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohadese Alemi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

shohadaye tajrish hospital, shahrdari st.Tajrish Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

198993415

**Phone**

+98 21 2274 9201

**Email**

alemi\_mohadese@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Noori Behnaz

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

shohadaye tajrish hospital, shahrdari st.Tajrish  
Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2247 9201

**Email**

Nouri@sbmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alemi Mohadese

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

shohadaye tajrish hospital, shahrdari st.Tajrish

Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2247 9201

**Email**

Alemi\_mohadese@sbmu.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Serum levels of vitamin D and lipid profile before surgery  
and 6 to 8 weeks after surgery

**When the data will become available and for how long**

6 months

**To whom data/document is available**

Researchers and Gynecologist

**Under which criteria data/document could be used**

For research and clinical use

**From where data/document is obtainable**

Dr. Behnaz Nouri by email Dr. Mohaddeh Alami by email

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

Contact the researcher

**Comments**