

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
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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

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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

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Province

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Phone

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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