

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of omega 3 fatty acids supplementation on uterine prostaglandin E2 and aromatase P450 in patients with leiomyoma

Protocol summary

Study aim

The effect of omega 3 fatty acids supplementation on uterine prostaglandin E2 and aromatase P450 in patients with leiomyoma

Design

Take uterine flushing and uterine biopsy from both groups in special days of menstrual cycles. Then we are going to give omega 3 for three months for the first group and again after taking drugs, biopsies of tissue and uterus fluid will be taken. In the first group, these topics will be studied before and after treatment: 2. numbers of pathologies in every patient and the biggest pathology in every patient.

Settings and conduct

Take uterine flushing and uterine biopsy from both groups in special days of menstrual cycles. Then we are going to give omega 3 for three months for the first group and again after taking drugs, biopsies of tissue and uterus fluid will be taken. In the first group, these topics will be studied before and after treatment: 2. numbers of pathology in every patient and the biggest pathology in every patient.

Participants/Inclusion and exclusion criteria

People in the age range of 25-40 years and they will enter the study with leiomyoma and patients with uterine obstruction, hormonal disorders, AUB, PCO and metabolic disorders, taking hormonal drugs and uterine polyps

Intervention groups

In this study, patients are divided into two groups. The control group (Lyomium-free and other diseases includes 10 patients diagnosed with leiomyoma that the beginning of the uterine fluid sample and uterine tissue, a cycle is taken on a specific day and will be treated with routine, but the intervention group (10 people) in addition to receiving routine treatment, they will receive an omega-3 gelatin capsule at a dose of 1,000 mg per day for 3 months. After 3 months, both groups will be examined again for the number of leiomyoma lesions and the size of the largest lesion in each patient.

Main outcome variables

Number and size of leiomyomas

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130115012146N7**

Registration date: **2020-07-05, 1399/04/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-05, 1399/04/15**

Update count: **0**

Registration date

2020-07-05, 1399/04/15

Registrant information

Name

Laaya Farzadi

Name of organization / entity

Woman's Reproductive Health Research Center of Tabriz

Country

Iran (Islamic Republic of)

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+98 41 1553 9161

Email address

farzadi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega 3 fatty acids supplementation on uterine prostaglandin E2 and aromatase P450 in patients with leiomyoma

Public title

The effect of omega 3 fatty acids supplementation on uterine prostaglandin E2 and aromatase P450 in patients with leiomyoma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 40-25 years Intra molar myomas are less than 50% prominent in the uterine cavity. Patients with leiomyoma who have been treated for myomas have not used hormonal drugs, including GnRH agonists, progesterone, and so on.

Exclusion criteria:

Patients with uterine obstruction, AUB, PCO and , taking hormonal drugs and Patients with hormonal disorders Patients with Polycystic ovary syndrome Patients with abnormal uterine bleeding Patients with metabolic disorders Patients taking hormonal drugs. Patients with uterine polyps

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht Street ,Tabriz University Of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2020-06-22, 1399/04/02

Ethics committee reference number

IR.TBZMED.REC.1399.312

Health conditions studied**1****Description of health condition studied**

Uterine Myoma

ICD-10 code

D25

ICD-10 code description

Leiomyoma of uterus

Primary outcomes**1****Description**

size of myoma

Timepoint

Three months after taking the drug

Method of measurement

sonography

2**Description**

Number of uterine fibroids

Timepoint

Three months after taking the drug

Method of measurement

sonography

Secondary outcomes**1****Description**

PGE2 levels in uterine fluid

Timepoint

Three months after taking the drug

Method of measurement

Measurement in the laboratory

2**Description**

The amount of aromatase and PGES genes

Timepoint

Three months after taking the drug

Method of measurement

Measurement in the laboratory

Intervention groups**1****Description**

Intervention group: we are going to take uterine flushing and uterine biopsy in special days of menstrual cycles . then we are going to give omega 3 for three months for intervention group and again after taking drugs , biopsies of tissue and uterus fluid will be taken

Category

Treatment - Drugs

2**Description**

Control group:Take Uterine flushing and uterine biopsy in special days of menstrual cycles

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Dr.Farzadi Laya

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Alzahra Hospital, South Artesh Ave

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5138663134

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+98 41 3553 9161

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Samiei

Street address

Third Floor, Central Building of Number2, Golgasht Street

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Farzadi Laaya

Position

Fellowship of Infertility

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

فلوشیپ نازایی

Latest degree

Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Latest degree
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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available