

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of Aromatase inhibitors in combination with oral contraceptive pills versus GnRH agonist on the treatment of uterine myoma

Protocol summary

Study aim

Evaluation of the Aromatase inhibitors in combination with oral contraceptive pills versus GnRH agonist on uterine myoma

Design

Phase 3 randomized clinical trial with parallel groups

Settings and conduct

This study will be conducted at Arash Women's Hospital on patients with uterine myomas. Participants will randomly be assigned into two groups; group 1 (Letrozole + OCP) and group 2 (Decapeptide Ampule). Once before and then once three months after the start of the intervention, information about demographic data and medical history will be collected through questionnaire. Pelvic pain and dysmenorrhea will be assessed by VAS monthly. Participants will be requested to record the amount of their menstrual bleeding and hot flashes. For all patients, serum tests will be measured. A radiologist will assess the uterine size and number, size, type, and the location of the fibroids by ultrasound. The degree of satisfaction with the treatment will be determined by a researcher-made questionnaire based on a Likert scale and the side effects of both treatments will be recorded.

Participants/Inclusion and exclusion criteria

Women aged 20 to 50 years, with at least 1 and a maximum of 5 uterine fibromas, with a size of more than 2 and less than 10 cm, will be included in the study if they have no malignancies or serious underlying diseases, and they do not need myomectomy.

Intervention groups

Group 1: Letrozole tablets + LD Group two: decapeptyl ampules

Main outcome variables

Vaginal Bleeding; Hemoglobin; Pelvic Pain; Myomas Size; Uterine Size; Number of Fibromas; Dysmenorrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140820018866N7**

Registration date: **2019-06-12, 1398/03/22**

Registration timing: **prospective**

Last update: **2019-06-12, 1398/03/22**

Update count: **0**

Registration date

2019-06-12, 1398/03/22

Registrant information

Name

Afsaneh Tehranian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 3283

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afsanehtehranian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Aromatase inhibitors in combination with oral contraceptive pills versus GnRH agonist on the treatment of uterine myoma

Public title

Effect of Aromatase inhibitors combination with oral contraceptive pills versus GnRH agonist on uterine myoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of at least one uterine myoma with a size of 2 centimeters (cm) or larger in ultrasound aged between 20 and 45 years old

Exclusion criteria:

Receiving other therapeutic strategies for treatment of the myoma Ovarian cyst or neoplasm Size of largest myoma larger than 10 cm More than 5 myomas Endometrial or cervical pathology exposure to hormonal agents in last month before the trial began Hepatic, cardiovascular and Renal diseases, peptic ulcer, malignancy, and other serious medical conditions Pregnancy or lactation Indication or tendency for surgical intervention

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

The considered sample size is 42, with 21 participant in each group. Block randomization method will be designed by using "www.sealedenvelope.com". The size of blocks considered is 6. The random allocation list for patients will be solely available to the epidemiologist. To hide the random allocation process, 42 card sequences of treatments will be written accordingly, and then the cards will be placed inside sealed envelopes. A 10-digit random code will be written on each packet as the patient's identification number. When the physician announces the eligibility of a patient, the methodologist will provide the envelope.

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

Ethics committee of Tehran University of Medical Science

Street address

Keshavarz Boulevard, Qods Street, Tehran University of Medical Science

City

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Postal code

1417653761

Approval date

2019-01-08, 1397/10/18

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.681

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

Average vaginal bleeding

Timepoint

Once before the intervention began, then 1, 2, and 3 months after the intervention began

Method of measurement

pictorial blood assessment chart

2

Description

Hemoglobin

Timepoint

Once before and once three months after the intervention began

Method of measurement

Blood Test

3

Description

Pelvic Pain

Timepoint

Once before and once three months after the intervention began

Method of measurement

Visual Analog Scale (VAS)

4

Description

Myoma Size

Timepoint

Once before and once three months after the intervention began

Method of measurement

Ultrasound

5

Description

Uterine Size

Timepoint

Once before and once three months after the intervention began

Method of measurement

Ultrasound

6

Description

Number of Fibroids

Timepoint

Once before and once three months after the intervention began

Method of measurement

Ultrasound

7

Description

Dysmenorrhea

Timepoint

Once before the intervention began, then 1, 2 , and 3 months after the intervention began

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Follicle Stimulating Hormone (FSH) Level

Timepoint

Once before and once three months after the intervention began

Method of measurement

Blood Test

2

Description

Luteinizing hormone (LH) Level

Timepoint

Once before and once three months after the intervention began

Method of measurement

Blood Test

3

Description

Bone Marrow Density (BMD)

Timepoint

Once before and once three months after the intervention began

Method of measurement

Dual Energy X-ray Absorptiometry

4

Description

Estradiol (E2) Hormone Level

Timepoint

Once before and once three months after the intervention began

Method of measurement

Blood Test

5

Description

Progesterone Hormone Level

Timepoint

Once before and once three months after the intervention began

Method of measurement

Blood Test

6

Description

Testosterone Hormone Level

Timepoint

Once before and once three months after the intervention began

Method of measurement

Blood Test

7

Description

Hot-flash

Timepoint

Daily

Method of measurement

Hot Flashes Diary

8

Description

Vitamin D3 Level

Timepoint

Once before and once three months after the intervention began

Method of measurement

Blood Test

Intervention groups

1

Description

Intervention group 1: Will receive one Letrozole 2.5 mg oral tablet plus one LD oral tablet per day, for a period of three months.

Category

Treatment - Drugs

2

Description

Intervention group 2: Will receive one decapeptyl 3.75 mg (made in France) IM injection every month, for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash women's hospital

Full name of responsible person

Dr Afsaneh Tehranian

Street address

No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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6th floor, Central University, Qods St, Keshavarz Blv, Tehran, Iran

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Web page address

<http://vcr.tums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr Niloofar Sadeghizadeh

Position

Gynecology Resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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niloofar.sz@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Afsaneh Tehranian

Position

Assistant Professor, Department of obstetrics and gynecology

Latest degree

Subspecialist

Other areas of specialty/work**Street address**

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Web page address**Latest degree**

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Niloufar Sadeghizadeh

Position

Gynecology Resident