Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of cabergoline, letrozole and triptorelin on the treatment of uterine myomas: a randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of cabergoline, letrozole and triptorelin on the treatment of uterine myomas.

Design

A randomized, parallel group, and single-blind trial without control group, phase 3 on 75 patients. Randomization will be computerized with concealed randomization sequence.

Settings and conduct

Setting: The gynecology clinic of Akbarabadi hospital, Tehran. Design: a parallel-group, single-blind, and randomized clinical trial on 75 patients with uterine myoma. Patients and data analyzer are unaware while physician is aware about the type of treatments. Interventions: Patients will be randomly divided into three groups and treated for 3 months from the first day of menstrual cycle. Respectively, the first, second, and third groups will be received letrozole (2.5 mg/day orally), cabergoline (0.5 mg/week), and triptorelin (2 mg once month) through intramuscular injection. Every three months, the effect of treatments on uterine myoma size, uterine size (ultrasonography), bleeding amount, the levels of lactate dehydrogenase, serum iron, and hemoglobin will be examined every three months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-45 years old women with uterine myoma. Exclusion criteria: patients above 45 years with a hemoglobin ≥ 9 g/dL, sustained myoma, severe bleeding, kidney and/or liver diseases, and anti-psychotic drug consumers.

Intervention groups

Control group: None First intervention group: Patients will be received letrozole (2.5 mg/day, orally) from the first to the 5th day of the menstrual cycle for 3 months. Second intervention group: Patients will be received cabergoline (0.5 mg/week, orally) for 3 months. Third intervention group: Patients will be received tryptorlin (2 mg) through intramuscular injection every 4 weeks for 3 months.

Main outcome variables

Uterine size; uterine bleeding amount; uterine myoma size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211212053372N1**
Registration date: **2021-12-21, 1400/09/30**
Registration timing: **prospective**

Last update: **2021-12-21, 1400/09/30**
Update count: **0**

Registration date

2021-12-21, 1400/09/30

Registrant information

Name

Nooshin Modaber

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 2221

Email address

modaber.n336@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-23, 1400/11/03

Expected recruitment end date

2022-03-26, 1401/01/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of cabergoline, letrozole and triptorelin on the treatment of uterine myomas: a randomized clinical trial

Public title
Comparison of the effect of cabergoline, letrozole and triptorelin on the treatment of uterine myomas: a randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
20-45 years old women with uterine myoma (size 3 to 8 cm) presenting bleeding and pelvic pain.

Exclusion criteria:
Patients who have a hemoglobin level of 9 grams per deciliter or higher and consume iron pills. Patients over the age of 45 years. Patients with basal myoma who have received hormonal treatment in the past three months. Patients with kidney and/or liver disease. Consumers of antipsychotic drugs. Patients with a history of drug treatment or surgery for uterine myoma with severe bleeding

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization type: Block randomization:blocks with size of 6 Randomization tool: www.sealedenvelope.com Random sequence concealment: Each patient's drug is placed into a matte envelope and an unique code assigned by www.sealedenvelope.com is pasted on every envelope.

Blinding (investigator's opinion)
Single blinded

Blinding description
This is a single blinded study. Drug intervention is the same for the three groups in terms of shape, color or appearance of drugs. Patients as well as data analyzer are unaware about the type of groups while physician investigator is aware about the type of groups or treatment intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Hemat Highway next to Milad Tower, Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2021-02-22, 1399/12/04

Ethics committee reference number
IR.IUMS.FMD.REC.1400.515

Health conditions studied

1

Description of health condition studied
Uterine myoma

ICD-10 code
D25.9

ICD-10 code description
Leiomyoma of uterus, unspecified

Primary outcomes

1

Description
Uterine size

Timepoint
At the beginning of the study (before the intervention) and three months later.

Method of measurement
Sonography

2

Description
Uterine bleeding amount

Timepoint
At the beginning of the study (before the intervention) and three months later.

Method of measurement
menstrual cup

3

Description
Uterine myoma size

Timepoint
At the beginning of the study (before the intervention) and three months later.
Method of measurement
Sonography

Secondary outcomes

1

Description
Lactate Dehydrogenase (LDH)
Timepoint
At the beginning of the study (before the intervention) and three months later.
Method of measurement
Lactate Dehydrogenase (LDH) Assay Kit (Colorimetric)

2

Description
Serum iron
Timepoint
At the beginning of the study (before the intervention) and three months later.
Method of measurement
Serum Iron Assay Kit (Colorimetric)

3

Description
Hemoglobin
Timepoint
At the beginning of the study (before the intervention) and three months later.
Method of measurement
Hemiglobincyanide method

4

Description
Possible clinical side effects of the drug (Including hot flashes, headaches, vaginal dryness and vomiting, etc.).
Timepoint
During and after 12 weeks of treatment.
Method of measurement
Clinical examination

Intervention groups

1

Description
First intervention group will be received Letrozole tab (2.5 mg once day, orally, Femara, Novartis, Basel Switzerland) for 3 months from the first day of the menstrual cycle.
Category
Treatment - Drugs

2

Description
Second intervention group will be received cabergoline tab (0.5 mg once week, orally, CABERLIN, Iran Hormone, Iran) for 3 months from the first day of the menstrual cycle.
Category
Treatment - Drugs

3

Description
Third intervention group will be received triptorelin syringe (2 mg once month, intramuscular, Femara, Novartis, Basel Switzerland)) for 3 months from the first day of the menstrual cycle.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecology clinic of Akbarabadi Hospital
Full name of responsible person
Shahnaz Ahmadi
Street address
Hemat Highway next to Milad Tower, Tehran
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1449614535
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Nooshin Modaber

Position

Physician and Gynecology and Obstetrics Assistante

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Shahnaz Ahmadi

Position

Professor of Obstetrics and Gynecology

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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