

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of cabergoline on myoma size and uterine bleeding in women with myomas attending to Arash Hospital

Protocol summary

Study aim

Determination of the effect of cabergoline on myoma size and uterine bleeding

Design

This study is designed as a double-blinded phase 3 controlled clinical trial, with parallel groups and a 1: 1 ratio. The sample size is considered to be 50.

Settings and conduct

This clinical trial is a double-blinded study of 50 women with uterine myomas referring to Arash Hospital's Gynecology Clinic. After the random allocation, the first group will be treated with the cabergoline tablets and the second group will be treated with the placebo.

Participants/Inclusion and exclusion criteria

Patients aged between 20 and 50 years old who have a myoma with a size of 3 to 8 cm; abnormal uterine bleeding and pelvic pain will be included in the study. Also, participants who are post-menopausal, have a pedunculated myoma, receiving hormonal treatments during the past 6 months, or suffering from any underlying serious diseases such as diabetes and liver disorders will not be recruited. Also, people who have a desire for myomectomy will not be included.

Intervention groups

Intervention group: 0.5 mg cabergoline tablet (weekly orally, 0.5mg Dostinex tablets per week made in Italy with a generic code of 00562 for 3 months). Control group: placebo tablet

Main outcome variables

Uterine bleeding, Size of liomyoma, drug tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170917036227N4**

Registration date: **2019-06-02, 1398/03/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-02, 1398/03/12**

Update count: **0**

Registration date

2019-06-02, 1398/03/12

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7771 9922

Email address

mvahid@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-02, 1398/01/13

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cabergoline on myoma size and uterine bleeding in women with myomas attending to Arash Hospital

Public title

Effect of cabergoline in treatment of uterine myoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Uterin bleeding and pelvic pain The size of the

leiomyoma is between 3 and 8 cm Aged between 20-50 years

Exclusion criteria:

Post menopause Pedunculated myoma Use of Hormonal or lipid-lowering agents during the last 6 months History of cardiovascular disease, venous thromboembolism, diabetes mellitus, liver and kidney disorders, hypertension Other malignancies Need or desire for lyomioma surgery in the next 3 months Pregnancy and lactation Uncontrolled hypertension

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method will be designed by an epidemiologist using STATA version 13 software. The number of blocks considered will be 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

The randomization list will be solely available to the epidemiologist. To hide the random allocation process, 50 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 and the type of treatment will be selected based on the type mentioned in the envelope. None of the patients should be aware of the type of treatment they are assigned to. The person who will evaluate the outcomes will be unaware of the random allocation process and type of treatments. Data analysis will be done by a statistician who is unaware of all processes performed.

Placebo

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 sciences

Street address

Zarafshan street, Qods town, Tehran

City

Tehran

Province

Tehran

Postal code

۸۱۴۵۵۶۱۸-۰۲۱

Approval date

2018-07-25, 1397/05/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.279

Health conditions studied

1

Description of health condition studied

leiomyoma

ICD-10 code

D25

ICD-10 code description

Leiomyoma of uterus

Primary outcomes

1

Description

The size of leiomyoma

Timepoint

Before and 3 month after intervention

Method of measurement

Ulthrasonography

2

Description

Uterine bleeding

Timepoint

Before and 3 month after intervention

Method of measurement

The number of bleeding days as well as the number of pads used

3

Description

Side effects of medication

Timepoint

Before and 3 month after intervention

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 0.5 mg cabergoline tablet (weekly orally, 0.5mg Dostinex tablets per week made in Italy with a generic code of 00562 for 3 months)

Category

Treatment - Drugs

2

Description

Control group: Placebo (composed of sugar and starch, in terms of shape, size and color, quite similar to cabergoline: weekly one, orally)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Linda Noozandejani

Street address

Eastern 162th St, Baghdarnia st, Resalat Highway, Tehranpars, Tehran ,Iran

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hosparash@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Qods St, Keshavarz Blv, Tehran, Iran

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Fax

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Email

rmo@tums.ac.ir

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 Marzieh Vahid Dastjerdi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Eastern 162th St.,Baghdarnia st.,Resalat Highway, Tehranpars, Tehran ,Iran.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Marzieh Vahid-Dastjerdi

Position

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Email

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Marzieh Vahid Dastjerdi

Position

Associate professor

Latest degree

Specialist

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because we have plan to use our data in another studies,
we are not interested to sharing the data at this time

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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