Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of cabergoline (dopamine receptor agonist) on the size and symptoms of uterine myoma in women with myoma.

Protocol summary

Summary

Objectives: Evaluation of the effect of cabergoline (dopamine receptor agonist) on uterine myoma. Design: Clinical trial Setting and conduct: single blind. Participants: 20-40 years old women with symptomatic myoma. Inclusion criteria: symptomatic myoma including abnormal uterine bleeding (after excluding the other etiologies), pelvic pain, and myoma in ultrasound with a minimum size of 2 centimeters. Exclusion criteria: severe bleeding; pregnancy; breast feeding; using any hormone or sedative; any other pathology in ultrasound;any known hormonal problems and any conditions need to an emergency treatment. Intervention: Group A, treatment with 0.5 mg cabergoline weekly for 3 months. Group B, observation for 3 months without cabergoline. Main outcome: minimum reduction of 20% in the size of myoma Other outcomes: reduction of the symptoms including pelvic pain, duration of the menstruation and amount of menstrual bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403092624N12**
Registration date: **2014-04-12, 1393/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-04-12, 1393/01/23

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-03-11, 1392/12/20

Expected recruitment end date

2015-03-10, 1393/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of cabergoline (dopamine receptor agonist) on the size and symptoms of uterine myoma in women with myoma.

Public title

Treatment of uterine myoma.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: symptomatic myoma including abnormal uterine bleeding (after excluding the other etiologies), pelvic pain, and myoma in ultrasound with a minimum size of 2 centimeters. Exclusion criteria : severe bleeding; pregnancy; breast feeding; using any hormone or sedative; any other pathology in ultrasound; any known hormonal problems and any conditions need to an emergency treatment.

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: **50**

Randomization (investigator's opinion)
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
Ethic committee of Tehran University of Medical Sciences.

Street address
Keshavarz Boulvard, Ghods Cross.

City
Tehran

Postal code

Approval date
2014-01-04, 1392/10/14

Ethics committee reference number
92/2298 /130/د

Health conditions studied

1

Description of health condition studied
fibromyoma of uterus

ICD-10 code
D25

ICD-10 code description
Leiomyoma of uterus; fibromyoma of uterus

Primary outcomes

1

Description
Change in the size of myoma.

Timepoint
3 months after treatment.

Method of measurement
Ultrasound

Secondary outcomes

1

Description
Change of the symptoms including pelvic pain and amount of bleeding.

Timepoint
3 months after treatment.

Method of measurement
Questionair and VAS

Intervention groups

1

Description
Intervention group:prescription of weekly 0.5 mg cabergoline for 3 months.

Category
Treatment - Drugs

2

Description
Control group: monitoring without drug prescription for 3 months.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Akbarabadi Teaching Hospital

Full name of responsible person
Maryam Kashanian

Street address
Molavi avenue, Molavi Cross.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research ,Iran University of Medical Sciences.

Full name of responsible person
Dr Seyed Javad Mousavi

Street address
Hemmat High way, Chamran Cross.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research ,Iran University of Medical Sciences.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Position

Professor.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty