

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparing the effect of Aromatase inhibitor (Letrozol) + Cabergoline (Dostinex) and letrozol alone on uterine myoma regression

Protocol summary

Summary

The objective of this randomized, clinical trial is comparing the effect of Aromatase inhibitor (Letrozol) + Cabergoline (Dostinex) and letrozol alone on uterine myoma regression. women with Myoma larger than 4 cm and irregular menstrual cycle; Candidate for myomectomy or hysterectomy or treatment of infertility Which referred to Al-Zahra hospital in Tabriz ,will be Checked. Patients were randomized using a random number table Random list of software Rand (Rand Company) are divided into two groups. This table has two rows and columns with a random number that matures in 99 rows and columns and rows and columns into blocks of five -digit numbers together and form were separated to facilitate its use. 38 people Patients with age over 45 years and Patients with a history of drug treatment or surgery for uterine myoma and uterine bleeding Will be excluded. Intervention Group (A) :Letrozole+ Dastinks and control group(B): Letrozole alone. In Group(A): Letrozole 2.5 mg per day and Dastinks 0.5 mg per week for 12 weeks from the first day of the period and in the control group: Letrozole 2.5 mg per day of the first day of the period. A week after the end of treatment and receiving the drug patients will be follow-up with using ultrasound . Primary Outcome in this study is Deterioration of uterine myoma deterioration of uterine myoma. This is not a blind study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506205283N12**

Registration date: **2015-08-22, 1394/05/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-22, 1394/05/31

Registrant information

Name

Manizheh Sayyah Melli

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2015-07-03, 1394/04/12

Expected recruitment end date

2016-07-02, 1395/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Aromatase inhibitor (Letrozol) + Cabergoline (Dostinex) and letrozol alone on uterine myoma regression

Public title

Comparing the effect of Aromatase inhibitor (Letrozol) + Cabergoline (Dostinex) and letrozol alone on uterine myoma regression

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: women with Myoma larger than 4 cm and irregular menstrual cycle; Candidate for myomectomy or hysterectomy or treatment of infertility
 Exclusion criteria: Age over 45 years; Uterine disease; Kidney disease; Liver disease; Antipsychotic drugs; Patients with history of use estrogen and progesterone in the last month; Patients with a history of drug treatment or surgery for uterine myoma and uterine bleeding

Age
 To 45 years old

Gender
 Female

Phase
 1-2

Groups that have been masked
No information

Sample size
 Target sample size: 76

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 Patients were randomized using a random number table
 Random list of software Rand (Rand Company) are divided into two groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Golgasht Street ,Tabriz University Of Medical Sciences

City

Tabriz

Postal code

Approval date

2015-06-13, 1394/03/23

Ethics committee reference number

TBZMED.REC.1394.264

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

Deterioration of uterine myoma

Timepoint

12 weeks after starting treatment

Method of measurement

Ultrasound

Secondary outcomes

1

Description

Menstrual regulation

Timepoint

After treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

The intervention group: Letrozole (Made in Iran , Iran hormone) 2.5 mg per day and Dostinex (Made in Iran , the company Aboureihaan) 0.5 mg per week for 12 weeks from the first day of the period

Category

Treatment - Drugs

2

Description

In the control group: Letrozole (Made in Iran , Iran hormone) 2.5 mg per day of the first day of the period

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Manizheh Sayyah-Melli

Street address

Alzahra Hospital, South Artesh Ave

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tabriz University Of Medical Sciences

Full name of responsible person

Dr. Alireza Rashidi

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

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, Tabriz 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

Tabriz University Of Medical Sciences

Full name of responsible person

Dr. Manizheh Sayyah-Melli

Position

prof. of Ob & Gyn

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