Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

The Effect of Letrozole on Symptomatic Uterine Leiomyoma in premenopausal women

Protocol summary

Summary

The purpose of this study is to evaluate the effect of treatment of uterine leiomyoma with letrozole therapy in premenopausal women. This research is a clinical trial study that 40 patient with including criteria (premenopausal women with age of 18-42 years and...) and excluding criteria (women with leiomyoma size of 2-5 cm and...) will be selected. It is recommended to the patients to use Letrozole which was produced by Soha Pharmaceutical Company with the dose of 2.5 mg/d for 12 weeks. The size of leiomyoma mass and the uterine volume is measured through trans-vaginal sonography in the first refer and the day of 30th and 90th after treatment. Blood exam is done in order to measure serum level of Estradiol, Gonadotropins and Hematocrit at the first, 30th and 90th day. It is asked from the patient to refer to the health office every 15 days. In these refers the patients is asked about the proper use of drugs for being certain, about the treatment side effects and also about the symptoms of leiomyoma.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402161760N32**
Registration date: **2014-07-05, 1393/04/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-05, 1393/04/14

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Babol University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Letrozole on Symptomatic Uterine Leiomyoma in premenopausal women

Public title

The Effect of Letrozole on Symptomatic Uterine Leiomyoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Premenopausal women aged 42-18 years with a single Intramural leiomyoma size> 5 cm; Women with uterine myoma> 5cm with other myoma size <2cm Exclusion criteria: Other women with myoma size> 2cm; Women with uterine leiomyomas treated with

estrogen or progesterone last month; Women with a history of major medical problems or previous medical or surgical treatment for leiomyomas; All women with leiomyoma sizes 2 to 5cm

Age
From **18 years** old to **42 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganjafroz Road

City
Babol

Postal code

Approval date
2014-06-09, 1393/03/19

Ethics committee reference number
4232

Health conditions studied

1

Description of health condition studied
Symptomatic Uterine Leiomyoma

ICD-10 code
D25

ICD-10 code description
Leiomyoma of uterus

Primary outcomes

1

Description
Leiomyoma tumors

Timepoint
On admission and on days 30 and 90 after treatment

Method of measurement
Ultrasound

2

Description
Uterine volume

Timepoint
On admission and on days 30 and 90 after treatment

Method of measurement
سونوگرافی

Secondary outcomes

1

Description
Serum gonadotropin

Timepoint
On admission and on days 30 and 90 after treatment

Method of measurement
Laboratory

2

Description
Serum Estradiol

Timepoint
On admission and on days 30 and 90 after treatment

Method of measurement
Laboratory

3

Description
Menstrual pattern

Timepoint
On admission and on days 30 and 90 after treatment

Method of measurement
clinical

4

Description
Clinical symptoms associated with leiomyoma

Timepoint
On admission and on days 30 and 90 after treatment

Method of measurement
clinical

Intervention groups

1

Description
Letrozole drug produced by the pharmaceutical company Soha the amount of 2.5mg / d is administered to patients for a period of twelve weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital Ayatollah Rouhani
Full name of responsible person
Dr. Asieh Khodami
Street address
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Babol University of Medical Sciences
Full name of responsible person
Dr. Ali Bijani
Street address
Vice Chancellor for Research of Babol University of Medical Sciences, Ganjafroz Avenue
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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
Vice Chancellor for Research of Babol 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
Hospital Ayatollah Rouhani
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Person responsible for updating data

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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