Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of letrozole on symptomatic uterine leiomyomas

Protocol summary

Summary

This study is a before and after controlled trial. 30 pre menopause patients, who have symptomatic liomyomatos equivalent or larger than 3 cm, take Letrozole (third generation of aromatase inhibitors). All of the patients who have this criteria are included and patients who have received hormonal therapy before this time, patients who have severe medical disorders and patients who have surgical treatment of myoma are excluded from this study. At the beginning of study uterine sonography is done and at the third day of menstrual cycle the level of FSH-LH -Stradiole and ferritine are measured. Data are collected from patients about symptoms for example pelvic pressure, frequency, pelvic pain, dysmenorhea, duration and volume of menstrual cycle and history of infertility. Patients are treated with 2/5 mg Letrozole daily for 90 days (continuously). At the end of study uterine sonograghy and noted lab tests are repeated and difference in clinical symptoms are asked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102015444N2**
Registration date: **2011-02-24, 1389/12/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-02-24, 1389/12/05

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research of Kashan University of Medical Sciences

Expected recruitment start date

2009-08-23, 1388/06/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of letrozole on symptomatic uterine leiomyomas

Public title

Evaluation of the effect of letrozole on symptomatic uterine leiomyomas

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : pre menopause patients who have symptomatic liomyomatos equivalent or larger than 3 cm. Exclusion criteria: patients who have received hormonal therapy; patients who have severe medical disorders; patients who have surgical treatment of myoma.

Age

From **20 years** old to **51 years** old

Gender

Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
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
Kashan university of medical sciences
Street address
Ghotb Ravandi Blvd, Pezeshk Blvd
City
Isfahan
Postal code
Approval date
2010-11-30, 1389/09/09
Ethics committee reference number
2438/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Uterine Liomyoma
ICD-10 code
N85.9
ICD-10 code description
Noninflammatory disorder of uterus, unspecified

Primary outcomes

1

Description
uterine leiomyomas size
Timepoint
before &90 days after 90 days treatment
Method of measurement
sonography

2

Description
uterine size
Timepoint
before &90 days after 90 days treatment
Method of measurement
sonography

Secondary outcomes

1

Description
FSH-LH
Timepoint
before & after 90 days treatment
Method of measurement
blood sampling

2

Description
stradiol
Timepoint
before & after 90 days treatment
Method of measurement
blood sampling

3

Description
ferritine
Timepoint
before & after 90 days treatment
Method of measurement
blood sampling

4

Description
patients symptoms
Timepoint
before & after 90 days treatment
Method of measurement
questionnaire

5

Description
hemoglobin
Timepoint
before & after 90 days treatment
Method of measurement
blood sampling

Intervention groups

1

Description
Letrozole tablet, 2/5 mg, daily for 90 days
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi center
Full name of responsible person
Street address
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research of Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Kashan University of Medical sciences
City
Kashan
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 Kashan 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
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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