

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 -Stradiol and ferritine are measured. Data are collected from patients about symptoms for example pelvic pressure, frequency, pelvic pain, dysmenorrhea, 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 sonography 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

Name

Mansoor Samimi

Name of organization / entity

Kashan

Country

Iran (Islamic Republic of)

Phone

+98 36 1446 0180

Email address

samimi_m@kaums.ac.ir

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

ferritin

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

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

Name of organization / entity

Kashan University of Medical sciences

Full name of responsible person

Dr Mansoureh Samimi

Position

Obstetrics & gynecologist

Other areas of specialty/work

Street address

Ghotb ravandy Blvd, Pezeshk Blvd

City

Kashan

Postal code

Phone

+98 36 1446 0180

Fax

Email

samimi_m@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical sciences

Full name of responsible person

Ms masoumeh abedzade

Position

MSc In Midwifery

Other areas of specialty/work

Street address

Ghotb ravandy Blvd, Pezeshk Blvd

City

Kashan

Postal code

Phone

+98 36 1555 0021

Fax

Email

abedzadeh@kaums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical sciences

Full name of responsible person

Dr. Masoumeh Abed

Position

Other areas of specialty/work

Street address

Ghotb ravandy Blvd, Pezeshk Blvd

City

Kashan

Postal code

Phone

+98 36 1446 0180

Fax

Email

M.malekin@yahoo.com

Web page address

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