

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of Letrozole and medroxy progesterone on premenopausal patient with endometrial hyperplasia: Randomized Clinical Trial

Protocol summary

Summary

One of the most common reasons of abnormal uterine bleeding is endometrial hyperplasia, leading to infertility and increased risk of endometrial cancer. This is a non-blind randomized clinical trial. The study population included 80 women referred to Abolfazle Clinic. Patients were divided into two groups based on the table of random numbers. Trial phase is 2-3. The diagnosis of endometrial hyperplasia was confirmed by pathology (curettage). Pathology report was simple endometrial hyperplasia. Inclusion criteria in the study consist of childbearing age women; lack of pregnancy and existence of simple endometrial hyperplasia in pathology report. Exclusion criteria in this research include non-reproductive ages; pregnancy; existence of complex hyperplasia with atypia in pathology report. Interventional group (40 patients) was treated by letrozole through a dosage of one tablet per day over three months. Control group (40 patients) received 10 mg of medroxy progesterone from day 16 to 25 three-months. The patients were rechecked up after three and six months. Also Transvaginal sonography and endometrial curettage were performed to evaluate the endometrial status. This study was conducted over a 3-year period from 2012 to 2014. We studied the effect of letrozole on endometrial thickness as well as reduction of irregular bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510244339N12**
Registration date: **2015-12-04, 1394/09/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-04, 1394/09/13

Registrant information

Name

Elham Rahmani

Name of organization / entity

Bushehr University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2012-04-27, 1391/02/08

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Letrozole and medroxy progesterone on premenopausal patient with endometrial hyperplasia: Randomized Clinical Trial

Public title

Letrozole in increasing endometrial thickness in Premenopausal patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women of reproductive age; non-pregnant; the diagnosis of endometrial hyperplasia as ultrasound and pathology. Exclusion criteria: side effects of letrozole; the prohibition of medicine prescription.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Bushehr University of Medical Sciences

Street address

Bushehr University of Medical Sciences, Alamdar St,
Salman Farsi St, Bushehr, Iran.

City

Bushehr

Postal code

Approval date

2011-04-28, 1390/02/08

Ethics committee reference number

3827

Health conditions studied

1

Description of health condition studied

Endometrial hyperplasia

ICD-10 code

N85.0

ICD-10 code description

Endometrial glandular hyperplasia

Primary outcomes

1

Description

The effect of letrozole on endometrial thickness

Timepoint

Three months and six months

Method of measurement

Transvaginal sonography

Secondary outcomes

1

Description

Reduction of irregular bleeding.

Timepoint

Three months and six months

Method of measurement

History of the patients

Intervention groups

1

Description

Control group (40 patients) received 10 mg of medroxy progesterone from day 16 to 25 three-months. The patients were rechecked up after three and six months. Also Transvaginal sonography and endometrial curettage were performed to evaluate the endometrial status.

Category

Treatment - Drugs

2

Description

Interventional group (40 patients) was treated by letrozole through a dosage of one tablet (2.5mg) per day over three months. The patients were rechecked up after three and six months. Also Transvaginal sonography and endometrial curettage were performed to evaluate the endometrial status.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Persian Gulf Martyrs Hospital

Full name of responsible person

Dr Elham Rahmani

Street address

Persian Gulf Martyrs Hospital, Borj square, Borj Blvd.

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research, Bushehr University of
Medical Sciences

Full name of responsible person

Dr Afshin Ostovar

Street address

Bushehr University of Medical Sciences, Alamdar St,
Salman Farsi St, Bushehr, Iran.

City

Bushehr

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor of research, Bushehr 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**

Bushehr University of Medical Sciences

Full name of responsible person

Dr Elham Rahmani

Position

Associate professor

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Person responsible for scientific inquiries

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Full name of responsible person

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Web page address

Person responsible for updating data

Contact

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