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
Country
Iran (Islamic Republic of)
Phone
+98 77125265914
Email address
rahmani@bpums.ac.ir

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
Other areas of specialty/work
Street address
Martyrs Hospital in Persian Gulf, Taleghani Street, Azadi Square, Bushehr, Iran
City
Bushehr
Postal code
Phone
+98 77333455374
Fax
Email
rahmani@bpums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bushehr University of medical Sciences
Full name of responsible person
Dr Elham Rahmani
Position
Associate professor
Other areas of specialty/work
Street address
Martyrs Hospital in Persian Gulf, Taleghani Street, Azadi Square, Bushehr, Iran
City
Bushehr
Postal code
Phone
+98 77 3345 5374
Fax
Email
rahmani@bpums.ac.ir
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