Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Letrozole versus Megestrol acetate for treatment of simple endometrial hyperplasia without Atypia

Protocol summary

Summary

Aims: Comparison between Letrozoleand Megestrol acetate in treatment of women having simple endometrial hyperplasia without Atypia; study design: Randomized (Balanced (permuted) block randomization) double-blind comparison of two drugs- Clinical Trial 2-3; Study population: women 44 to 50 years; Main inclusion criteria: The presence of hyperplasia without Atypi in endometrial biopsy, Unusual diameter of endometrial, Unusual abnormal uterine bleeding; Main exclusion criteria: Performing hormone therapy during the last 6 months, wanting to get pregnant for at least3months from now, Focal endometrial lesions such as Leiomyoma , having Atypical or complex hyperplasia, Breast-feeding, history of vascular disease or clotting disorders, Hypertension؛ Sample size: Two groups of 25 individuals, a total of 50 people ; Study intervenes: Women 44 to 50 years old, complaining about abnormal uterine bleeding will have ultra sound terrace vaginal basis by the Sonography unit. In case of having a thick abnormal endometrium, the will have endometrial biopsy by pathologists unit using Pipelle method. Serum estradiol levels will also be calculated. After identifying women suffering from simple endometrium hyperplasia without cytologic atypical, they will divided into two groups. The first group will be prescribed Megestrol acetate, and the second group will be prescribed Letrozole. After the end of treatment, the serum estradiol level will be calculated. The Patients will have endometrial biopsy three to four weeks after the end of treatment, and the results will be compared; Intervention time: After diagnosing Women suffering from simple endometrium hyperplasia without cytologic Atypia; Outcome measures: Abnormal thickening of the endometrium (more than 12 millimeter) along with abnormal uterine bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031011504N5**
Registration date: **2015-12-12, 1394/09/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-12, 1394/09/21

Registrant information

Name
Sanam Moradan
Name of organization / entity
Semnan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Semnan University of Medical Sciences

Expected recruitment start date

2015-06-15, 1394/03/25

Expected recruitment end date

2016-09-15, 1395/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Letrozole versus Megestrol acetate for treatment of

simple endometrial hyperplasia without Atypia

Public title
Compare the effect of the drug Letrozole and Megestrolto treat abnormal uterine bleeding
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age 44 to 50 years, Having abnormal uterine Hemorrhage, simple hyperplasia without Atypia present in the endometrial biopsy, agreement to take part in the study, abnormal thickening of the endometrium (more than 12millimeterin reproductive age sand the pre- menopausal or the presence of endometrium 5 to 12millimeters in reproductive ages and pre- menopausal along with abnormal bleeding continuation despite medical treatment) intrans vaginal ultrasound(first evaluation via basic trans-vaginal ultrasound will be done for all research units by the sonography and in case of abnormal endometrium thickness (more than12millimeters), these people will inter the study; Exclusion criteria: Performing hormone therapy during the last 6 months, wanting to get pregnantfor at least 3 months from now, focal endometrial lesions such as Leiomyoma, having Atypi color complexly perplasia, flushing symptoms, Sleep Disorders, mood changes during the last 3 months, Breast-feeding, Having congenital uterine disorders, Hypothyroidism, Hypertension, history of vascular disease or clotting disorders, sensitivity to Progestin’s.
Age
From **44 years** old to **50 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Semnan University of Medical Sciences
Street address
Semnan University of Medical Sciences, Basij Boulevard,Semnan
City
Semnan
Postal code
3519899951
Approval date
2015-06-15, 1394/03/25
Ethics committee reference number
IR.SEMUMS.REC.1394.18

Health conditions studied

1

Description of health condition studied
simple hyperplasia
ICD-10 code
N80-N98
ICD-10 code description
No inflammatory disorders of female genital trac

Primary outcomes

1

Description
Endometrial hyperplasia without Atypia simple cytologic
Timepoint
Before and after the intervening
Method of measurement
Trans-vaginal ultra sound and endometrial biopsy basis

2

Description
Abnormal uterine bleeding
Timepoint
Before and after the interference(the twentieth to twenty fourth day of menstrual cycle)
Method of measurement
Trans-vaginal ultra sound and endometrial biopsy basis

3

Description
Premenopausal
Timepoint
Before and after the interference(20 to 24menstrual cycles)
Method of measurement
Measuring the serum level of follicle-stimulating hormone

Secondary outcomes

1

Description

Estradiol

Timepoint

Before and after the intervention.

Method of measurement

Serum levels of Estradiol

2

Description

Endometrial thickness

Timepoint

Before and after the intervening

Method of measurement

The wall thickness of the Endometrial based on ultrasound

3

Description

side effects of taking Letrozole and Megestrol acetate

Timepoint

Once per month

Method of measurement

Genera sensitivity, itching, hives and monthly sonography

4

Description

triglyceride

Timepoint

Before and after the intervention

Method of measurement

Blood levels of triglycerides

5

Description

Cholesterol

Timepoint

Before and after the intervention

Method of measurement

Blood levels of cholesterol

6

Description

Menstrual status

Timepoint

Before and after the intervention

Method of measurement

Oligomenorrhea, Polymenorrhea ,normal

Intervention groups

1

Description

He first group will be prescribed 40 milligram of Megestrol acetate (40 milligram BRENDOCARE tablet, made by Aburaihan pharmaceutical co. Iran) for two weeks in each month (A 40 milligram tablet per day). After the end of treatment, all the research units will investigate (interview and trans-vaginal Sonography) the serum Estradiol levels after the interference. The Patients will have endometrial biopsy three to four weeks after the end of treatment, and the results before and after that will be compared. The results will be investigated by international standards.

Category

Treatment - Drugs

2

Description

The second group will be prescribed 2.5 milligram of Letrozole (2.5 milligram Letrax tablet, made by Aburaihan pharmaceutical co. Iran), for two months, A tablet per day. After the end of treatment, all the research units will investigate (interview and trans-vaginal Sonography) the serum Estradiol levels after the interference. The Patients will have endometrial biopsy three to four weeks after the end of treatment, and the results before and after that will be compared. The results will be investigated by international standards.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Niaz Nik Khah

Street address

Imam Hossein Square

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Semnan University of Medical Sciences

Full name of responsible person

Dr Mohamad Reza Asgari

Street address

Basij Boulevard

City

Semnan

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 and Technology, Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Dr Niaz Nik Khah

Position

Gynecology resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

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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