

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

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

Protocol summary

Summary

Aims: Comparison between Letrozole and 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 Atypia 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 least 3 months 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, they 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 be 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)

Phone

+98 23 1446 0066

Email address

smoradan@sem.ums.ac.ir

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
General 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
The 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

Street address

Amiralmomenin Hospital, Imam Hossein Square,
Semnan

City

Semnan

Postal code

3519899951

Phone

+98 23 3346 1433

Fax

Email

niaz_nik@yahoo.com

Web page address

Semnan

Postal code

3519899951

Phone

+98 23 3346 1433

Fax

Email

sm42595@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Samaneh Lavvaf

Position

BS of Statistics/Expert Abnormal Uterin Bleeding
Research Center

Other areas of specialty/work

Street address

Abnormal Uterin Bleeding Research Center,
Amiralmomenin Hospital, mam Hossein Square,
Semnan

City

Semnan

Postal code

3519899951

Phone

+98 23 3346 1433

Fax

Email

sama_lavvaf@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Sanam Moradan

Position

Associate Professor/ Gynecologist

Other areas of specialty/work

Street address

Amiralmomenin Hospital, Imam Hossein Square,
Semnan

City

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