

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparative effectiveness of letrozole and methformin on endometrial histology in patients with disordered proliferative endometrium and simple hyperplasia utreus cancer in alzahra hospital.

Protocol summary

Summary

The main objective of this study is The effect of letrozole and methformin on endometrial histology in patients with disordered proliferative endometrium and simple hyperplasia utreus cancer. This study will be conducted on 90 women with abnormal uterine bleeding were referred to the Alzahra hospital. They are done for endometrial biopsy and pathology reports, endometrial hyperplasia or endometrial cancer or abnormal proliferative glands have been reported. If they are allergic to letrozole, metformin and severe liver disease, uncontrolled hypertension, thromboembolism will be excluded. Patients are divided into three groups according to the type of event. All patients concurrently administered drug letrozole (made in Iran, Iran Hormone) 2.5 mg BID and 500 mg BID metformin for three months. After 3 months to be taken again from the people endometrial biopsy specimens were reviewed by 2 pathologists. Results of before and after treatment will be compared by a Gynecologic Oncology and Pathology results can be considered as the primary outcome to compare the response to treatment in patients with pathological criteria. If the diagnosis of endometrial cancer, endometrial biopsies at the time just to prepare the patient for surgery, both drugs given at least two weeks then, before the intervention compared with biopsy confirmed after hysterectomy. This is a not blinded study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412085563N6**
Registration date: **2015-01-03, 1393/10/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-03, 1393/10/13

Registrant information

Name

Elaheh Ouladsahebmadarek

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1554 1221

Email address

madarek@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research,Tabriz University Of Medical Sciences

Expected recruitment start date

2014-12-14, 1393/09/23

Expected recruitment end date

2016-08-10, 1395/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effectiveness of letrozole and methformin on endometrial histology in patients with disordered proliferative endometrium and simple hyperplasia utreus cancer in alzahra hospital.

Public title

The effect of letrozole and methformin on endometrial histology in patients with disordered proliferative endometrium and simple hyperplasia utreus cancer.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with abnormal uterine bleeding and having disordered proliferative or hyperplastic endometrium and uterine cancer; Consent to participate
Exclusion criteria: People who are allergic to metformin and letrozole, severe impairment of hepatic function; Uncontrolled high blood pressure; Thromboembolism

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

N/A

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

Vice chancellor for Research, Tabriz University Of Medical Sciences

Street address

Golgasht Street, Tabriz University Of Medical Sciences

City

Tabriz

Postal code

Approval date

2014-06-26, 1393/04/05

Ethics committee reference number

9347

Health conditions studied

1

Description of health condition studied

Patients with abnormal bleeding and endometrial proliferative and Hayrplastyk with irregular glands

ICD-10 code

N85.0

ICD-10 code description

Endometrial glandular hyperplasia

Primary outcomes

1

Description

Histologic types of endometrial

Timepoint

Three months after the first dose

Method of measurement

Microscopic examination

Secondary outcomes

empty

Intervention groups

1

Description

In the third group with cervical cancer: Drug letrozole (made in Iran, Iran Hormone) 2.5 mg BID and 500 mg BID Metformin is prescribed for three months.

Category

Treatment - Drugs

2

Description

Group II endometrial proliferative effect: Drug letrozole (made in Iran, Iran Hormone) 2.5 mg BID and 500 mg BID Metformin is prescribed for three months.

Category

Treatment - Drugs

3

Description

The first group with abnormal uterine bleeding: Drug letrozole (made in Iran, Iran Hormone) 2.5 mg BID and 500 mg BID Metformin is prescribed for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Elaheh Ouladsahebmadarek

Street address

Alzahra Hospital, South Artesh Ave

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Alireza Rashidi

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

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,Tabriz 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

Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Elaheh Ouladsahebmadarek

Position

Prof. of Ob & Gyn

Other areas of specialty/work

Street address

Golgasht Street, Tabriz University Of Medical Sciences

City

Tabriz

Postal code

5138665793

Phone

+98 41 3553 9161

Fax

Email

wrhrcenter@gmail.com; lahroudin@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Elaheh Ouladsahebmadarek

Position

Prof. of Ob & Gyn

Other areas of specialty/work

Street address

Golgasht Street, Tabriz University Of Medical Sciences

City

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

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Dr.Elaheh Ouladsahebmadarek

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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