

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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 uterine 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 Hyperplasty 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**

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## Person responsible for scientific inquiries

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**Position**

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## Person responsible for updating data

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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*