Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of metformin-megestrol combination and megestrol alone on endometrial histology in patients with disordered proliferative or hyperplastic endometrium.

Protocol summary

Summary

The objective of this randomized, clinical trial is to investigate the effect of metformin and megestrol with megestrol only on histologic endometrial cells in patients with proliferative and hyperplastic endometrium without atypia. 84 patients in equal groups, 42 participant in each group with abnormal uterine bleeding and having disordered proliferative or hyperplastic endometrium without atypia who have consent to participate were included. Patients who have allergy to metformin, who have renal failure, nausea, vomiting, anorexia, anemia, cutaneous lesions or not satisfied to participate in the study, were excluded. In the first group, metformin 500 mg twice a day with megestrol 40 mg daily and the other group of megestrol acetate (brand Jstyran, made in Persia, now Iran Hormone) will be prescribed 40 mg daily for 3 months. 2 weeks after discontinuation of therapy, again each endometrial biopsy was performed and the pathological samples will be compared to their treatment. Early outcome measures include improvement of the symptoms, response to treatment and endometrial histology.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410275283N11**
Registration date: **2014-11-28, 1393/09/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-28, 1393/09/07

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research,Tabriz University Of Medical Sciences

Expected recruitment start date

2014-11-21, 1393/08/30

Expected recruitment end date

2017-04-30, 1396/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of metformin-megestrol combination and megestrol alone on endometrial histology in patients with disordered proliferative or hyperplastic endometrium.

Public title

Comparison of metformin-megestrol combination and megestrol alone on endometrial histology in patients with disordered proliferative or hyperplastic endometrium.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with abnormal uterine bleeding and havingdisordered proliferative or hyperplastic endometrium with or without atypia; Consent to participate. Exclusion criteria: Patients who have allergy to metformin; Patients with renal failure; nausea, vomiting, anorexia; anemia; cutaneous lesionsor not satisfied to participate in the study.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **84**

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

ice chancellor for Research,Tabriz University Of Medical Sciences

Street address

Golgasht Street ,Tabriz University Of Medical Sciences

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Postal code

Approval date

2014-11-15, 1393/08/24

Ethics committee reference number

93121

Health conditions studied

1

Description of health condition studied

Patients with abnormal bleeding and endometrial proliferative and Hayprplastyk with irregular glands with and without atypia

ICD-10 code

N85.0

ICD-10 code description

Endometrial glandular hyperplasia

Primary outcomes

1

Description

Endometrial pathology

Timepoint

Before surgery

Method of measurement

Pathological evaluation

2

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 first group, metformin 500 mg twice a day with megestrol 40 mg daily

Category

Treatment - Drugs

2

Description

The second group of megestrol acetate 40 mg daily for 3 months will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Manizheh Sayyah-Melli

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Alzahra Hospital, South Artesh Ave

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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

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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