

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

Name

Manizheh Sayyah Melli

Name of organization / entity

Tabriz University of Medical Sciences

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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 having disordered 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 lesions or 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

City

Tabriz

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 Hayprlastyk 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

Street address

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

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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**

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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