Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of Metformin and Megestrol acetate on endometrial histology in patients with disordered proliferative or hyperplastic endometrium. A RCT

Protocol summary

Summary

Recently several studies have shown that the anti-diabetic biguanide metformin have a protective effect against some types of cancer including endometrial carcinoma. The objective of this randomized, clinical trial is to investigate the effect of metformin compared to megestrol acetate on endometrium in patients with menorrhagia who diagnosed to have disordered proliferative or hyperplastic endometrium without atypia. Sixty patients in equal groups, 15 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. First group will receive metformin which is started by 500mg orally in the morning for one week, then twice daily for the second week, and 500mg in the morning + 1000mg at night for the third week. Finally all patients in metformin group will receive 850 mg metformin twice daily for 3 months. The second group will receive megestrol acetate 40mg/day for 3 months. After three months both groups will undergo endomertrial biopsy. Early outcome measures include improvement of the symptoms, response to treatment and endometrial histology.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205265283N4**
Registration date: **2013-03-16, 1391/12/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-03-16, 1391/12/26

Registrant information

Name

Manizheh Sayyah Melli

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 3741

Email address

sayyahmellim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-08-20, 1391/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Metformin and Megestrol acetate on endometrial histology in patients with disordered proliferative or hyperplastic endometrium. A RCT

Public title

Comparing the effect of Metformin and Megestrol acetate

on endometrial histology in patients with disordered proliferative or hyperplastic endometrium. A RCT

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

From **20 years** old to **60 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Tabriz University of medical Sciences

Street address

Golgasht Ave., Vice Chancellor deputy of Research, Tabriz University of medical Sciences

City

Tabriz

Postal code

Approval date

2012-04-18, 1391/01/30

Ethics committee reference number

862/4/5

Health conditions studied

1

Description of health condition studied

Patients with abnormal uterine bleeding and have disordered proliferative or hyperplastic endometrium with or without atypia

ICD-10 code

N85.0

ICD-10 code description

Endometrial glandular hyperplasia

Primary outcomes

1

Description

Endometrialpathology

Timepoint

before surgery

Method of measurement

Pathologic assessment

2

Description

Endometrial Histologic type

Timepoint

Three months after medical therapy

Method of measurement

Microscopic assessment

Secondary outcomes

empty

Intervention groups

1

Description

First group: fifteen cases with disordered proliferative endometrium , 15 cases with hyperplastic atypical endometrium and 15 cases with hyperplasticendometrium and without atypia who referred to Alzahra Teaching Hospital, are included and after getting written informed consent, metformin is given for 3 months, then endometrial biopsy will be carried out and the response to therapy will be compared according to the pathologic results.

Category

Treatment - Drugs

2

Description

Second group: fifteen cases with disordered proliferative endometrium , 15 cases with hyperplastic atypical endometrium and 15 cases with hyperplastic endometrium and without atypia who referred to Alzahra Teaching Hospital, are included and after getting written informed consent, megestrol acetate is given for 3 months, then endometrial biopsy will be carried out and the response to therapy will be compared according to the pathologic results.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Manizheh Sayyah-Melli

Street address

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Elaheh Ouladsahebmadarek

Street address
Alzahra Hospital, South ArteshAve.,Tabriz, Iran.

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Women's Reproductive Health Research Center, 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
Manizheh Sayyah-Melli

Position
Full Professor

Other areas of specialty/work

Street address
South Artesh Ave.,Tabriz, Iran.

City
Tabriz

Postal code

Phone
+98 41 1553 9161

Fax

Email
manizheh.sayyahmelli@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
Manizheh Sayyah-Melli

Position
Full Professor

Other areas of specialty/work

Street address
South ArteshAve.,Tabriz, Iran.

City
Tabriz

Postal code

Phone
+98 41 1553 9161

Fax

Email
manizheh.sayyahmelli@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person
Manizheh Sayyah-Melli

Position

Other areas of specialty/work

Street address

City

Postal code

Phone
00

Fax

Email
manizheh.sayyahmelli@gmail.com

Web page address

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