

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of melatonin and megestrol acetate compared to megestrol acetate alone on endometrial histology in patients with endometrial proliferative disorders: a double blind randomized clinical trial

Protocol summary

Study aim

The effect of melatonin on endometrial histology in patients with endometrial proliferative disorders

Design

This study is a clinical trial with a control group, with parallel groups. It is double-blind and randomized. This phase 3 study will be conducted on 40 patients. In this study, simple random allocation method will be used.

Settings and conduct

In this study, patients with menorrhagic complaints who are referred to the clinics of Al-Zahra Hospital in Tabriz will be included in the study. Patients in the control group will receive routine treatment with megestrol acetate, and patients in the intervention group will receive megestrol acetate + melatonin. Patients will be observed for 3 months and endometrial biopsy will be performed in the third month. Participants, pathologists and data analysts will be blinded to the study groups.

Participants/Inclusion and exclusion criteria

Patients with complaints of menorrhagia, if diagnosed with endometrial proliferative disorders or atypical hyperplasia, will be included in the study, and if they have a history of hormone therapy in the last 3 months and do not consent to participate in the study, they will be prohibited from entering the study.

Intervention groups

Patients in the control group, will be treated with megestrol acetate at a daily dose of 80mg and Patients in the intervention group, will be treated with megestrol acetate at a daily dose of 80 mg + melatonin at a daily dose of 5 mg before bedtime for three months. Patients will be observed for 3 months.

Main outcome variables

Histologic types of endometrium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120922010901N10**

Registration date: **2023-05-08, 1402/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-08, 1402/02/18**

Update count: **0**

Registration date

2023-05-08, 1402/02/18

Registrant information

Name

Parvin Mostafa Gharebaghi

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin and megestrol acetate compared to megestrol acetate alone on endometrial histology in patients with endometrial proliferative disorders: a double blind randomized clinical trial

Public title

The effect of melatonin on endometrial histology in patients with disordered simple hyperplasia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 38 to 55 years Women with abnormal uterine bleeding and proliferative endometrium with irregular glands Willingness to participate in the study BMI between 18.5 and 29.99

Exclusion criteria:

Atypical hyperplasia and endometrial cancer diagnosis History of hormone therapy in the last 3 months Not consent to participate in the study Diabetes History of depression and use of antidepressants Coagulation disorders Hypertension Seizures and the use of antiepileptic drugs Having autoimmune diseases

Age

From **38 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple random allocation method will be used. In this method, a list of numbers from 1 to 40 will be prepared. In this list, numbers are randomly divided. Depending on the time of the patient's visit, one of these numbers will be assigned to the patient, and based on the created list and being even or odds, the patients will be assigned to the intervention and the control groups. The intervention group will be even numbers and the control group will be odd numbers. Then, the sealed envelope method will be used for concealment. In this way, each number will be written on a card and then placed inside the envelopes. We will glue the lids of the envelopes and put them in the boxes. for Participants in order of entering, one of the envelopes will be opened and the assigned group to that participant will be determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs are blindly coded while they are manufactured uniform and the participant and clinical caregiver will be unaware of their content. In addition, pathology results without mentioning the type of treatment performed on the patient, with headings A and B will be provided to the analyst to evaluate the consequences. So, these people will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor, Nnumber 2 Central Building, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2023-04-05, 1402/01/16

Ethics committee reference number

IR.TBZMED.REC.1402.060

Health conditions studied

1

Description of health condition studied

Endometrial hyperplasia

ICD-10 code

N85.0

ICD-10 code description

Endometrial hyperplasia

Primary outcomes

1

Description

Histologic types of endometrium

Timepoint

Three months after the first dose of the drug

Method of measurement

Microscopic examination

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients in the control group, will be treated with megestrol acetate at a daily dose of 80mg (Aboureihan Pharmaceuticals Iran]). Patients will be observed for 3 months and endometrial biopsy will be performed in the third month by the same fellow pathologist.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in the intervention group, will be treated with megestrol acetate at a daily dose of 80 mg (Aboureihan Pharmaceuticals [Iran]) + melatonin at a daily dose of 5 mg (Galinus Pharmaceuticals, Iran) before bedtime for three months. Patients will be observed for 3 months and endometrial biopsy will be performed in the third month by the same fellow pathologist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr. Parvin Mostafa Gharabaghi

Street address

Alzahra Hospital, South Artesh St., Tabriz, Iran

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alzahrahosp@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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research-vice@tbzmed.ac.ir

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parvin Mostafa Gharabaghi

Position

Gynecologist, fellow of Women's Oncology / Associate Professor Obstetrics Midwifer

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parvin Mostafa Gharabaghi

Position

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available