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 magesterol 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
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Iran (Islamic Republic of)
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+98 41 1553 9161
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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, Nnmber 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
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Alzahra Hospital, South Artesh St.,Tabriz, iran
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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.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