

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of herbal mixture extract on endometrial histology in patients with disordered proliferative endometrium and simple hyperplasia.

Protocol summary

Pathological results are considered as the main outcome of this study.

Study aim

The effect of herbal mixture extract on endometrial histology in patients with disordered proliferative endometrium and simple hyperplasia.

Design

80 women divided into equal groups who are matched for not having long term exposure to estrogen or progesterone and don't have female neoplastic disorders. Patients are randomly divided into two groups A & B based on Randlist software.

Settings and conduct

After standardization of herbal mixture (Curcuma longa, Citrus sinensis, Vitex agnus-castus and, Melissa officinalis) final formulation according to Food and Drug Administration (FDA), by the Pharmaceuticals International Company, the Clinical Trial study will be carried out. Patients in the control group will receive Megestrol Acetate 40 mg daily for three months with placebo (500 mg) daily and in the intervention group, patients will receive Megestrol acetate 40 mg daily with a combination of 500 mg of plant extract daily for three months. Then, in the two groups, endometrial histology will be studied. After 3 months, endometrial biopsy is performed and samples are investigated by two pathologists. The results are compared before and after treatment by a gynecologist.

Participants/Inclusion and exclusion criteria

All women over 18 years of age have abnormal uterine bleeding and proliferative endometrium with irregular glands

Intervention groups

Intervention group will consume Megestrol Acetate (40 mg)(made in Iran, Abooreyhan company) daily along with a medicinal herb mixture (500 mg) daily for three months. Patients in the control group will receive Megestrol Acetate (40 mg) daily with placebo(which is similar in shape, size and color to herbal medicine) (500 mg) daily for three months.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120922010901N9**

Registration date: **2022-01-16, 1400/10/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-16, 1400/10/26**

Update count: **0**

Registration date

2022-01-16, 1400/10/26

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-10, 1400/10/20

Expected recruitment end date

2023-01-10, 1401/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of herbal mixture extract on endometrial histology in patients with disordered proliferative endometrium and simple hyperplasia.

Public title

The effect of herbal mixture extract on endometrial histology in patients with disordered simple hyperplasia.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with abnormal uterine bleeding and proliferative endometrium with irregular glands Willingness to participate in the study Lack of sensitivity to the plants used in the study

Exclusion criteria:

Thromboembolism Severe liver dysfunction High blood pressure

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

First, we will do the randomization using the program (www.graphpad.com). 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

Patients are then randomly divided into two groups (A and B). Patients in the control group will receive placebo with megestrol. Then the 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

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, Central Building of Number2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.TBZMED.REC.1400.856

Health conditions studied**1****Description of health condition studied**

malignant neoplasm of female genital organs

ICD-10 code

C54.1

ICD-10 code description

malignant neoplasm of female genital organs

Primary outcomes**1****Description**

Endometrial histology

Timepoint

Before intervention, three months after intervention

Method of measurement

Endometrial biopsy

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group will consume Megestrol Acetate (40 mg) daily along with a medicinal herb mixture (500 mg) daily for three months

Category

Treatment - Drugs

2

Description

Control group:Patients in the control group will receive Megestrol Acetate (40 mg) daily with placebo(which is similar in shape, size and color to herbal medicine) (500 mg) daily for three months.

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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Gharabagh.p@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. Parvin Mostafa Gharabaghi

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Gologasht 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

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Person responsible for updating data

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Position

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Professor Obstetrics Midwifer

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City

Tabriz

Province

East Azarbaijan

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