Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of melatonin supplementation with progesterone on the improvement and level of inflammatory factors in patients with endometrial hyperplasia

Protocol summary

Study aim
The effect of melatonin supplementation with progesterone on the improvement and level of inflammatory factors in patients with endometrial hyperplasia
Design
A clinical trial with a randomized three-blind control group performed on 20 people.
Settings and conduct
The present study is a three-way blind with random assignment using a random number table.
Participants/Inclusion and exclusion criteria
Patients with endometrial atypical hyperplasia, without a history of treatment, referred to the clinic of Beheshti Hospital in Kashan, after obtaining informed consent
Intervention groups
The case group contains two 5 mg medroxyprogesterone tablets and two 10 mg melatonin tablets.
Main outcome variables
Pathological manifestations of the uterus

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220116053735N1**
Registration date: **2022-06-19, 1401/03/29**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-19, 1401/03/29**
Update count: **0**
Registration date
2022-06-19, 1401/03/29

Registrant information
Name
Neda Aslany
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-03-20, 1400/12/29
Expected recruitment end date
2023-02-19, 1401/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of melatonin supplementation with progesterone on the improvement and level of inflammatory factors in patients with endometrial hyperplasia

Public title
The effect of melatonin supplementation with progesterone on the improvement and level of inflammatory factors in patients with endometrial hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with endometrial atypical hyperplasia, without a

history of treatment, referred to the clinic of Beheshti Hospital in Kashan,

Exclusion criteria:

Pregnancy

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in the form of a table of random numbers. Random number table is a set of numbers that are produced without a specific pattern or order and in a completely random manner and has become a table. To use a table of random numbers, the table is first pre-set for reading numbers (for example, up, down, left, or right), the second assumption is to consider numbers for different groups (for example, even numbers for intervention A and Individual numbers for intervention B) Then the researcher touches one of the numbers and moves in one of the predetermined directions and records the numbers and assigns them to different groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Due to the fact that in the present study, placebo was used to eliminate any bias in the effectiveness of drugs, participants, researchers and clinical caregivers were blinded. Each participant is assigned a code based on the type of drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Kashan

City

Kashan

Province

Isfehan

Postal code

8565215487

Approval date

2021-12-05, 1400/09/14

Ethics committee reference number

IR.KAUMS.REC.1400.051

Health conditions studied

1

Description of health condition studied

Hyperplasia

ICD-10 code

E32.0

ICD-10 code description

Persistent hyperplasia of thymus

Primary outcomes

1

Description

One consequence of the study is the lack of observation of hyperplastic lesions in pathology examination and report of secondary pathology. Another consequence is an increase in the levels of the above inflammatory factors in re-testing by ELISA at the end of the fourth month of treatment.

Timepoint

monthly

Method of measurement

In this study, interviews and observations and researcher-made checklists were used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Two medroxyprogesterone 5 mg tablets (manufactured by Caspian) and two 10 mg melatonin tablets (manufactured by Galenus) are given every night from the fifteenth day of the cycle for two weeks to three one-month periods.

Category

Treatment - Drugs

2

Description

Control group: Two medroxyprogesterone 5 mg tablets and two placebo tablets are prescribed every night from the fifteenth day of the cycle for two weeks to three one-month periods.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Shahid Beheshti Hospital
Full name of responsible person
Neda Aslany
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamidreza Banafsheh
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Neda Aslany
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Position
Resident

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Gynecology and Obstetrics

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No. 403,mehregan building, koohe noor Ave., Shafaq Blvd., Keshavarz Blvd

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
Get permission from the project manager

From where data/document is obtainable
By email

What processes are involved for a request to access data/document
Email request

Comments