Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparing the Effect of Melatonin with Placebo in Combination with Medroxy Progesterone in Women with Polycystic Ovarian Syndrome

Protocol summary

Study aim

Specific goals: 1. Comparison of changes in the ratio of LH to FSH in patients before and after the intervention, between the two groups receiving melatonin and placebo 2. Determining the effectiveness of melatonin in improving the quality of life in PCOS patients (based on PCOSQ questionnaire) 3. Comparison of changes in BMI in patients before and after the intervention, between the two groups receiving melatonin and placebo 4. Determining the effectiveness of melatonin in improving hirsutism in PCOS patients (based on Ferriman-Gallwey scoring system) Practical purposes: Finding a new strategy in the treatment of patients with PCOS

Design

Two arm parallel groups, double-blinded, randomized by permuted block randomization method, phase 2 clinical trial with 88 patients

Settings and conduct

This research will be performed in the gynecology clinic of Shariati hospital and in the field of PCOS. After two-way blindness and randomization, patients are divided into two groups. They will receive the mentioned medicines for 12 weeks. Necessary checks are done before starting and after finishing.

Participants/Inclusion and exclusion criteria

Inclusion: Women in reproductive age who diagnosed with PCOS based on Rotterdam criteria. most of the patients are new cases. Exclusion: Breastfeeding, adrenal hyperplasia, hyperprolactinemia, mental disorders, hypothyroidism.

Intervention groups

Intervention group: 6mg melatonin daily + 10 mg medroxyprogesterone since 16th day of cycle for two weeks Control group: placebo + 10 mg medroxyprogesterone since 16th day of cycle for two weeks

Main outcome variables

The main consequence is improving the clinical symptoms of a PCOS patient, which is achieved by reducing the ratio of LH to FSH, weight, hirsutism, and improving the quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200711048078N1**
Registration date: **2020-08-27, 1399/06/06**
Registration timing: **prospective**

Last update: **2020-08-27, 1399/06/06**
Update count: **0**

Registration date

2020-08-27, 1399/06/06

Registrant information

Name

Fatemeh sadat Ayati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2278 0091

Email address

fsayati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-29, 1399/08/08

Expected recruitment end date

2021-05-24, 1400/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the Effect of Melatonin with Placebo in Combination with Medroxy Progesterone in Women with Polycystic Ovarian Syndrome

Public title
Effect Evaluation of Melatonin in treatment of Polycystic Ovarian Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women in reproductive age (18-45) Women diagnosed with PCOS, based on Rotterdam criteria Who doesn't want to get pregnant for at least 3 months Most of patients are new cases If the patient has a medical history of taking medicines, should discontinue medications for at least 3 months before entering the study

Exclusion criteria:
Breastfeeding Wants to get pregnant Adrenal Hyperplasia Hyper Prolactinemia Mental Disorders Hypothyroidism Patients using hormonal medications or medications that cause weight loss and weight gain who's on a diet

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted Block Randomization: Random division is done in the form of "blocks" with a predetermined size and the number of people is evenly distributed among the study groups. Randomization unit: individual Randomization Tools: Statistical Software

Blinding (investigator's opinion)
Double blinded

Blinding description
The process of research will be explained to the patients and a consent form will be obtained from them, but we do not inform them which group they belong to. In this research, the researcher and the advisor are clinical caregivers who do not know which patient is taking the drug and which is taking a placebo by using the coding method. The only person who knows what group each patient belongs to is the supervisor who knows the coding.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of The Institute of Pharmaceutical Sciences-Tehran University of Medical Sciences

Street address
16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences

City
Tehran

Province
Tehran

Postal code
14155-6451

Approval date
2020-06-30, 1399/04/10

Ethics committee reference number
IR.TUMS.TIPS.REC.1399.031

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
LH (luteinizing hormone) to FSH (follicle stimulating hormone) ratio

Timepoint
Measurement of blood LH and FSH levels at the beginning and end of the study

Method of measurement
Blood test

2

Description
BMI (body mass index)

Timepoint

Measurement of height and weight at the beginning and end of the study

Method of measurement

Scale and stadiometer

3

Description

Quality of life

Timepoint

At the beginning and end of the study

Method of measurement

PCOSQ (polycystic ovarian syndrome quality of life questionnaire)

4

Description

Hirsutism

Timepoint

At the beginning and end of the study

Method of measurement

Ferriman-Gallwey scoring scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For 12 weeks, in addition to receiving basic treatment (from day 16 of the cycle for two weeks, 10 mg of medroxyprogesterone per night), she takes 6 mg of melatonin daily, as well as at night before bedtime.

Category

Treatment - Drugs

2

Description

Control group: For 12 weeks, in addition to receiving basic treatment (from day 16 of the cycle for two weeks, 10 mg of medroxyprogesterone per night), she takes placebo daily, as well as at night before bedtime.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology clinic of Shariati hospital

Full name of responsible person

Fatemeh sadat Ayati

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North Kargar street

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1411713135

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hossein Ghahremani

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Faculty of pharmacy, tehran university of medical science, 16 Azar street, Enghelab street

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh sadat Ayati

Position

Student

Latest degree

A Level or less

Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information about the main outcome can be shared. Such as age, height, weight, LH and FSH concentration
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
Available for pharmacists working in industry and clinics and obstetricians
Under which criteria data/document could be used
Please be contacted before using the information.
From where data/document is obtainable
Fatemeh sadat Ayati Mobile: 00989120338404 Non-academic Email: fsayati@gmail.com University Email: fs-ayati@student.tums.ac.ir
What processes are involved for a request to access data/document
Please be contacted before using the information.
Comments