

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of melatonin on the sleep quality of patients with chronic pelvic pain caused by endometriosis, a triple-blind randomized controlled trial study in the provider unit

Protocol summary

Study aim

The effect of melatonin on the sleep quality of patients with chronic pelvic pain caused by endometriosis

Design

A triple blind parallel randomized controlled trial

Settings and conduct

In the run-in phase of the study medical student and gynecologist will be present at endometriosis clinic in the Fatemehzahra infertility center 4 days in a week. All participants have an identifiable sleep disturbance by PSQI global score ≥ 5 , followed by a confirmed diagnosis of chronic pelvic pain according to visual analog scale. Demographic characteristics and a complete medical history will be obtained at the initial visit as well as through a clinical interview including age, occupation, body mass index, pelvic pain intensity, medical and drug history, endometriosis pelvic ultrasound findings, and endometriosis laparoscopy findings. All eligible participants will be asked to sign a written informed consent. PSQI will be completed before and after 2 months of intervention. The drug and placebo are similar in terms of appearance, and the patients, the outcome assessor, and the statistician will be unaware of the allocation of the drugs.

Participants/Inclusion and exclusion criteria

- 18- 45 years of age, who had complained of endometriosis with EACPP, and Sleep disturbances based on PSQI questionnaire (score ≥ 5).
- No history of surgical or medical treatments for infertility.
- Not smoking, drinking alcohol, and addiction to substance.
- Lack of systemic illness diseases, such as diabetes, blood pressure, seizures.

Intervention groups

Group A includes patients receiving melatonin and group B includes patients receiving placebo.

Main outcome variables

change in sleep quality according to (PSQI)

questionnaire, endometriosis associated pelvic pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171209037794N4**

Registration date: **2023-07-07, 1402/04/16**

Registration timing: **prospective**

Last update: **2023-07-07, 1402/04/16**

Update count: **0**

Registration date

2023-07-07, 1402/04/16

Registrant information

Name

Parvaneh Mirabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8898 7958

Email address

parvaneh_mirabi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-16, 1402/04/25

Expected recruitment end date

2023-10-12, 1402/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin on the sleep quality of patients with chronic pelvic pain caused by endometriosis, a triple-blind randomized controlled trial study in the provider unit

Public title

melatonin and sleep quality

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The eligibility of each included patients will be confirmed by the gynecologist. Subjects eligible for the study must meet all of the following criteria at randomization: •18-45 years of age, who had complained of endometriosis with EACPP, and Sleep disturbances based on PSQI questionnaire (score ≥ 5). •No history of surgical or medical treatments for infertility. •Not smoking, drinking alcohol, and addiction to substance. •Lack of systemic illness diseases, such as diabetes, blood pressure, seizures

Exclusion criteria:

•continuous use of sleeping pills, anticoagulants and anticonvulsants •women treated with antidepressants •use of stimulants or hypnotics or anti-anxiety medications •recent diagnosis of mood disorders or neuropsychiatric symptoms (within 8 weeks) •pregnancy or breastfeeding •known hypersensitivity to melatonin •If the patient does not want to continue to participation •Ongoing or previous pharmacologically treated depression or bipolar disorder •Work involving nightshifts

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization will be used to achieve balance in the allocation of participants to intervention arms. Before initiation of the run-in phase of the study, two 80- sets of random numbers will be created by a member of the research team not involved in recruitment. Twenty blocks with size of 4 and combination of A for the melatonin and B for placebo group will be prepared. A randomization will be made by

using a dedicated online software

(<http://www.randomization.com>). Allocation sequence will be password-protected and only accessible to the independent investigator not involved in the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Administration of medication type will be triple-blinded. The patient, the outcome assessor and the statistical analyst will be blinded. Blinding of medication conditions will be conducted by a pharmacist at Shahid Beheshti University of Medical Sciences. Placebo capsules will be lactose and cellulose and will be identical in size and appearance to the melatonin capsule (Jalinous Pharmaceutical Company).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

Street address

Ganj Afrooz

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Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2023-07-03, 1402/04/12

Ethics committee reference number

MUBABOL.HRI.REC.1402.041

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

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

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

sleep quality
Timepoint
Before and 2 months after intervention
Method of measurement
PSQI-19 questionnaire

Secondary outcomes

1
Description
pelvic pain
Timepoint
Before and two months after the intervention
Method of measurement
VAS score

Intervention groups

1
Description
Intervention group: patients will receive 5 mg melatonin tablet once a day for 2 months.
Category
Treatment - Drugs

2
Description
Control group: patients will receive placebo once a day for 2 months.
Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Fatemehzahra infertility center
Full name of responsible person
parvaneh mirabi
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parvaneh_mirabi@yahoo.com

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
mehdi rajabnia
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ramazan69@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
parvaneh mirabi
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
infertility and reproductive health
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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Data on the main outcome will be available

When the data will become available and for how long

Access period starts 6 months after the publication of results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

It's not specified yet.

From where data/document is obtainable

Dr Parvaneh Mirabi parvaneh_mirabi@yahoo.com

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

Two weeks after application

Comments

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

parvaneh mirabi

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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