Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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 Fatemezahra 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
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Iran (Islamic Republic of)
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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

Fatemezahra infertility center

Full name of responsible person

parvaneh mirabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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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

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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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