

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Investigation of the effect of oral melatonin on the thickness of the endometrium of infertile women in the IUI cycle

Protocol summary

Study aim

Determination of the effect of oral melatonin on the thickness of the endometrium of infertile women in the IUI cycle

Design

A randomized clinical trial with two intervention groups, with parallel groups, without blinding, on 104 patients and the kitset.ir website was used for randomization.

Settings and conduct

104 infertile patients who referred to the women's clinic of Imam Sajjad Hospital in Yasuj and will undergo intrauterine sperm insemination(IUI) will randomly and without blinding divided into two groups:receiving melatonin and placebo (52 patients in each group).First, all patients are treated with clomiphene and letrozole, twice a day from the 3rd to the 7th day of menstruation, and then injectable gonadotropin injected on the 8th, 9th,and 10th days.If the thickness of the endometrium bu ultrasound is less than6 mm, 2 mg estradiol prescribe from the 8th day of menstruation.In the group with low endometrial thickness,6 mg melatonin prescribe and uterine endometrium thickness check again on the 11th and 14th day.On the 14th to 16th day of the cycle, if there are 1 to 2 suitable follicles, HCG ampoule is injected and 36 hours later IUI is performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: full consent to participate in the study, BMI less than 35, women with low endometrial thickness, no history of hospitalization and underlying diseases
Exclusion criteria: male infertility, simultaneous uterine anomalies, fallopian tube blockage, having a history of endometriosis, AFC less than 10

Intervention groups

The intervention group, 6 mg of melatonin and the control group, the placebo medicine which contains cellulose and will be similar to melatonin pills in terms of shape, size and taste will consume from the 3rd day of menstruation (daily) until the end of the cycle for one month before sleep and after 4 pm.

Main outcome variables

Endometrial thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221127056633N1**

Registration date: **2023-04-03, 1402/01/14**

Registration timing: **prospective**

Last update: **2023-04-03, 1402/01/14**

Update count: **0**

Registration date

2023-04-03, 1402/01/14

Registrant information

Name

Zohreh Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7788

Email address

zohre1a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

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

Investigation of the effect of oral melatonin on the thickness of the endometrium of infertile women in the IUI cycle

Public title

The effect of melatonin on endometrial thickness

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Full consent to participate in the study BMI less than 35
Women with low endometrial thickness No history of hospitalization and underlying diseases

Exclusion criteria:

Male infertility Simultaneous uterine anomalies
Obstruction of uterine tubes Having a history of endometriosis AFC less than 10

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method is used, in which the randomization unit is individual, and the random sequence generation software (Random Number Generator software) is used, and for the purpose of concealment, the concealment of random allocation is used. By using opaque letter envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Yasouj University of Medical Sciences

Street address

Deputy of research and technology of Yasuj University of Medical Sciences, Shahid motahari boulevard, Yasuj city, Kohgiluyeh and Boyer-Ahmad province, Iran.

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2022-11-25, 1401/09/04

Ethics committee reference number

IR.YUMS.REC.1401.094

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

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

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

Endometrial thickness

Timepoint

Measurement of endometrial thickness at the beginning of the study and 11 and 14 days after starting melatonin

Method of measurement

Ultrasound sonography

Secondary outcomes

empty

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

Intervention group: In this group, 6 mg of melatonin which is prepared by Razak Pharmaceutical Company will be consumed from the 3rd day of menstruation (daily) until the end of the cycle for one month, before going to bed and from 4 pm onwards.

Category

2**Description**

Control group: In this group, the placebo, which contains cellulose and will be similar to melatonin pills in terms of shape, size and taste and it is prepared by Razak Pharmaceutical Company, is consumed from the 3rd day of menstruation (daily) until the end of the cycle for one month, before going to bed and from 4 pm onwards.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Sajad Hospital

Full name of responsible person

Shahin Taj Aramesh

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Next to Azadi hotel, Yasuj city, Kohgiluyeh and Boyer-Ahmad province, Iran.

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<http://emamsajad.yums.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Seyyed Amin Hosseini

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Deputy of research and technology of Yasuj University of Medical Sciences, Shahid motahari boulevard, Yasuj city, Kohgiluyeh and Boyer-Ahmad province, Iran.

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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

Yasouj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Shahin Taj Aramesh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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