Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)
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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 boulvared, Yasuj city, Kohgiluyeh and Boyer-Ahmad province, Iran.
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
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

Treatment - Drugs

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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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 boulvared, 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
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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