

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of melatonin supplementation for ovarian stimulation cycles on sleep and mood and microinjection outcomes in patients with polycystic ovary syndrom

Protocol summary

Study aim

Determination of the effect of melatonin supplementation in ovarian stimulation cycle on micro injection outcomes(number and quality of oocytes and embryos) in patient with poly cystic ovary syndrome

Design

Clinical trial with control group

Settings and conduct

patients visits and treatments and follow up and oocytes pick up are performed with the gynecologists in Avicenna infertility center clinics and operation room

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 to 40 years old, Having symptoms of polycystic ovary syndrome.
Exclusion criteria: Azospermia in sperm analysis of male partner, The use of alternative infertility treatment services, Uncontrolled medical condition, Abnormal karyotype, Uterine abnormal anatomy, Immune and coagulation dysfunction

Intervention groups

Intervention group get melatonin treatment 3 mg daily (nature made company) for 6 weeks before oocyte pick up. In intervention group and control group ovarian stimulation with gonadotropins is started from the third day of the menstrual cycle (after one period of oral contraceptive pill use) and ovarian response is monitored serially in the gynecologist visits and trans vaginal Sonography , and when the ovarian follicles reach to the appropriate size, oocyte pick up is performed under the vaginal Sonography guide with general anesthesia.

Main outcome variables

Number and quality of retrieved oocytes, Fertilization rate, Number and quality of embryos

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160717028967N10**
Registration date: **2019-06-07, 1398/03/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-07, 1398/03/17**

Update count: **0**

Registration date

2019-06-07, 1398/03/17

Registrant information

Name

Safora Salemi

Name of organization / entity

Shahid Chamran University of Ahvaz

Country

Iran (Islamic Republic of)

Phone

+98 83 3821 1001

Email address

e.mahmoudi@cobeldarou.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin supplementation for ovarian stimulation cycles on sleep and mood and microinjection outcomes in patients with polycystic ovary syndrome

Public title

The effect of melatonin in patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 to 40 years old Having symptoms of polycystic ovary syndrome candidate of micro-injection for infertility treatment

Exclusion criteria:

Azospemia in sperm analysis of male partner The use of alternative infertility treatment services Uncontrolled medical condition Abnormal karyotype Uterine abnormal anatomy Immune and coagulation dysfunction

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two equal groups (A and B) based on a randomized six-block table that is designed by Random allocation software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Avicinna infertility center

Street address

Avicenna Infertility Treatment Center, No 97, Yakhchal-Shariati junction, Shariati street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1941913114

Approval date

2019-03-05, 1397/12/14

Ethics committee reference number

IR.ACECR.AVICENNA.REC.1398.002

Health conditions studied

1

Description of health condition studied

Poly Cystic Ovary Syndrome

ICD-10 code

E28.2

ICD-10 code description

Poly cystic ovarian syndrome

Primary outcomes

1

Description

Number of retrieved oocytes

Timepoint

on the day of oocyte pick up

Method of measurement

Microscopic Assessment of oocytes count by the embryologist

2

Description

Fertilization rate

Timepoint

The fertilization rate will be checked on the day after sperm injection

Method of measurement

Is calculated as percentage transformation of micro injected oocytes in to two pronuclei

3

Description

Number of embryos

Timepoint

The time of the assessment is 3 days after fertilization

Method of measurement

Microscopic assessment of the embryos count by the embryologist

4

Description

Sleep

Timepoint

Before the intervention and after 6 weeks

Method of measurement

Pittsburgh sleep quality index questionnaire, STOP Bang questionnaire and insomnia severity index questionnair

5

Description

Depression

Timepoint

Before the intervention and after 6 weeks

Method of measurement

Beck depression short Inventory

6

Description

Quality of retrieved oocytes

Timepoint

on the day of oocyte pick up

Method of measurement

Microscopic assessment of the oocytes morphology by the embryologist

7

Description

Quality of embryos

Timepoint

The time of the assessment is 3 days after fertilization

Method of measurement

Microscopic assessment of the embryos morphology by the embryologist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Melatonin 3 mg tablets (nature made company) daily with oral contraceptive pill and Folic Acid start from the third day of the menstrual cycle before stimulation of ovaries and are continued till the oocyte pick up after the ovarian stimulation with the antagonist method in the next menstrual cycle(for 6 week)

Category

Treatment - Drugs

2

Description

Control group: Oral contraceptives and folic acid start from the third day of menstrual cycle and oocyte pick up after ovarian stimulation with antagonist method will be performed in the next menstrual cycle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Avecinna infertility center

Full name of responsible person

Soheila Ansaripour

Street address

Avicenna Infertility Treatment Center, No 97, Yakhchal-Shariati junction, Shariati street, Tehran, Iran

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Postal code

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Phone

+98 21 23519

Email

Soh.ansaripour@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Avicenna infertility center

Full name of responsible person

Sharare Shafiei

Street address

Avicenna Infertility Treatment Center, No 97, Yakhchal-Shariati junction, Shariati street, Tehran, Iran

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sh.shafiei@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Avicenna infertility center

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

Avicenna infertility center

Full name of responsible person

Dr. Soheila Ansari pour

Position

Assistant professor of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Email

Soh.ansari pour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Avicenna infertility center

Full name of responsible person

Dr. Soheila Ansari pour

Position

Assistant professor of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Avicenna infertility center

Full name of responsible person

Katayoun Yazdchi

Position

fellowship of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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