

# 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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1941913114

#### **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

##### **City**

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##### **Province**

Tehran

##### **Postal code**

1941913114

##### **Phone**

+98 21 23519

##### **Email**

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

**Street address**

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

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**Postal code**

1941913114

**Phone**

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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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**Postal code**

1941913114

**Phone**

+98 21 23519

**Email**

Soh.ansari pour@gmail.com

## 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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Avicenna Infertility Treatment Center, No 97,  
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Iran

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**Postal code**

1941913114

**Phone**

+98 21 23519

**Email**

katayounyazdchi@yahoo.com

## 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