

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **Feasibility evaluation of secretome obtained from menstrual blood derived stem cells accompanied with melatonin and follicular fluid in oocyte maturation of patients with polycystic ovary syndrome (PCOS).**

#### **Protocol summary**

##### **Study aim**

Feasibility evaluation of secretome obtained from menstrual blood derived stem cells accompanied with melatonin and follicular fluid of non polycystic ovary syndrome patients in patients with polycystic ovary syndrome in order to improve oocyte maturation and assessment of embryos quality compared to control group.

##### **Design**

The clinical trial involves 4 groups including the control group plus 3 experimental groups in which the immature oocytes of 90 patients were non-randomly distributed.

##### **Settings and conduct**

The study will be performed at Avicenna Infertility Treatment Center on immature oocytes of polycystic ovary syndrome women. Immature oocytes in the germinal vesicle (GV) stage, which are not clinically usable, will be collected post ovulation of the patients who filled informed consent. Matured oocytes will be assessed for the expression of maturation-related genes and apoptotic genes using Polymerase Chain Reaction (PCR).

##### **Participants/Inclusion and exclusion criteria**

Among infertile women who visit the clinic: polycystic ovary syndrome women, ages under 40 yrs, Anti Mullerian hormone higher than 1.3, at least 4 immature oocytes and non male factor, are included. Non polycystic ovary syndrome women, unable to give informed consent, immature oocytes under 4, Anti Mullerian hormone under 1.3, background disease and infectious disease hepatitis C virus, human immunodeficiency virus (HIV) and hepatitis B, will be excluded.

##### **Intervention groups**

The study groups involve 4 groups for each individual containing the routine medium used for oocyte culture in the laboratory as a control, stem cell secretome, the

secretome and melatonin, the secretome and melatonin and the follicular fluid added to the routine medium.

##### **Main outcome variables**

Oocyte maturation, embryo development, embryo quality, expression of oocyte maturation related genes and expression of apoptotic genes.

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20180619040147N8**

Registration date: **2021-10-19, 1400/07/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-19, 1400/07/27**

Update count: **0**

##### **Registration date**

2021-10-19, 1400/07/27

##### **Registrant information**

##### **Name**

Maryam Darzi

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 21 2243 2020

##### **Email address**

m.darzi@ari.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2021-10-12, 1400/07/20

##### **Expected recruitment end date**

2022-05-20, 1401/02/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Feasibility evaluation of secretome obtained from menstrual blood derived stem cells accompanied with melatonin and follicular fluid in oocyte maturation of patients with polycystic ovary syndrome (PCOS).

**Public title**

In Vitro Maturation of oocyte

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Polycystic ovary syndrome patients No background disease At least 4 immature oocyte Anti Mullerian hormone (AMH) higher than 1.3 No male factor

**Exclusion criteria:**

Unable to give informed consent Background disease Immature oocyte lower than 4 Infectious disease human immunodeficiency virus (HIV), hepatitis C virus (HCV) and Hepatitis B.

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **4**

at least 4 immature oocytes from each patient will be enrolled in 4 groups.

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In this study for the first time, secretome obtained from menstrual blood derived stem cells accompanied with melatonin and follicular fluid of non poly cystic ovary syndrome patients in oocyte maturation will be evaluated.

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee in research of Avicenna Research Institute

**Street address**

Avicenna Research Institute, Shahid Beheshti University, Shahid Chamran Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969412

**Approval date**

2021-08-24, 1400/06/02

**Ethics committee reference number**

IR.ACECR.AVICENNA.REC.1400.013

**Health conditions studied**

**1**

**Description of health condition studied**

In Vitro Maturation of oocyte

**ICD-10 code**

**ICD-10 code description**

**2**

**Description of health condition studied**

Polycystic ovarian syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**

Polycystic ovarian syndrome

**Primary outcomes**

**1**

**Description**

Oocyte maturation

**Timepoint**

24 hours

**Method of measurement**

Detecting polar body under stereoscope

**Secondary outcomes**

**1**

**Description**

Embryo development after ICSI (Intra Cytoplasmic Sperm Injection)

**Timepoint**

24 and 48 hours after ICSI

**Method of measurement**

2PN and cell division assessment under stereoscope

## 2

### Description

Embryo quality

### Timepoint

48 and 72 hours after ICSI

### Method of measurement

Embryo assessment under stereoscope

## 3

### Description

Gene expression

### Timepoint

24 hours after treatment

### Method of measurement

PCR (Polymerase Chain Reaction)

## Intervention groups

## 1

### Description

Intervention group: Immature oocytes

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Avicenna Infertility Center

#### Full name of responsible person

Dr. Somaieh Kazemnejad

#### Street address

Yakhchal St. Shariati St.

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## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Iranian academic center for education culture and research

#### Full name of responsible person

Mohammad-Reza Sadeghi

#### Street address

Avicenna Research Institute, Shahid Beheshti

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#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Grant given from Ministry of Science to Top researcher in 2020

#### 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

Iranian academic center for education culture and research

#### Full name of responsible person

Hilda Rastegari

#### Position

Laboratory Expert

#### Latest degree

Master

#### Other areas of specialty/work

Microbiology

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## Person responsible for scientific

## **inquiries**

### **Contact**

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Iranian academic center for education culture and research

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**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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## **Person responsible for updating data**

### **Contact**

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**Position**

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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**

No - There is not 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**

Not applicable

**Data Dictionary**

Not applicable