

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

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Tehran

Province

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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

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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

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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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Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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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