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)

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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
Ғeasibility 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
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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
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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