Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the therapeutic effect of very small stem cells from peripheral blood on improving the results of In Vitro Fertilization (IVF) cycles in diminished ovarian reserve patients.

Protocol summary

Study aim

Evaluation of the therapeutic effect of Very Small Stem Cells(VSSC) from peripheral blood on improving the In vitro fertilisation(IVF) out comes in Diminished ovarian reserve (DOR) patients.

Design

This pilot, phase 1, non-randomized, non- blinding clinical trial will be conducted in the form of a before and after study in the group of patients who are eligible to enter the study. Considering the newness of the study and the discussion of stem cells therapy in infertility, the number of 15 couple is considerated.

Settings and conduct

At least 15 patients referred to the infertility department of Taleghani Hospital will be included in the study. Before starting, blood levels of FSH, LH, estradiol and AMH and the number of antral follicles are measured by vaginal ultrasound on the third day of menstruation. Blood FSH, LH, estradiol and AMH levels and AFC are checked again after 3 menstrual periods and on the third day of bleeding. Then the patients are placed in antagonist IVF cycle.

Participants/Inclusion and exclusion criteria

Women aged forty and under, with the diagnosis of DOR, have a history of IVF cycle failure in the last year and infertile couples who are fully satisfied with the work steps and want to repeat the IVF cycle 3 months after treatment.

Intervention groups

The patients are in the follicular phase, ampule Granulocyte colony-stimulating factor with dose of 5mg/kg with subcutaneous methods and Periumbilical will be injected(daily for 4 days). Sampling is done, 3 hours after injecting the last dose of ampule, 120 cc of blood is taken and subjected to apheresis. VSSCs reextracted from peripheral blood and 2 cc are injected into each ovary under sedation and vaginal ultrasound guidance in the operating room.

Main outcome variables

The number of follicles formed, the total number of oocytes and the total number embryos obtained in the cycle after treatment with stem cells.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230420057968N1**
Registration date: **2023-06-15, 1402/03/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-15, 1402/03/25**
Update count: **0**

Registration date

2023-06-15, 1402/03/25

Registrant information

Name

Hajar Abbasi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-07, 1402/02/17

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the therapeutic effect of very small stem cells from peripheral blood on improving the results of In Vitro Fertilization (IVF) cycles in diminished ovarian reserve patients.

Public title
Evaluation of the effect of very small stem cells from peripheral blood on the results of IVF cycles in diminished ovarian reserve patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with a calendar age of 40 and under Women diagnosed with diminished ovarian reserve Women with a history of IVF cycle failure in the last year The infertile couple should be fully satisfied with the procedure Couples who want to repeat the IVF cycle three months after this treatment
Exclusion criteria:
Dissatisfaction of the infertile couple Women with autoimmune diseases Women with endometriosis Women with ovarian cancer Women with breast cancer Women with poly cystic ovarian syndrome Women with infectious diseases such as hepatitis and acquired immunodeficiency virus Women with ovarian failure secondary to hypothalamic and pituitary disorders A couple diagnosed with recurrent miscarriage A couple do not give consent
Age
To **40 years** old
Gender
Female

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
22431607
Approval date
2023-03-05, 1401/12/14
Ethics committee reference number
IR.SBMU.REC.1402.001

Health conditions studied

1

Description of health condition studied
infertility due to diminished ovarian reserve
ICD-10 code
N97.0
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
The number of oocytes obtained in the IVF cycle after ovarian stem cells therapy
Timepoint
Before the start of the intervention and after 3 months of ovarian stem cells therapy in IVF cycle again
Method of measurement
Counting under the microscope

2

Description
The total number of embryos obtained in the IVF cycle after ovarian stem cells therapy
Timepoint
Before the start of the intervention and after 3 months of ovarian stem cells therapy in IVF cycle again
Method of measurement
Counting under the microscope

Secondary outcomes

1

Description
evaluation the number of clinical pregnancies in the IVF cycle after ovarian tuberculosis therapy
Timepoint
3 months after ovarian stem cells therapy in the IVF cycle again in terms of clinical pregnancy(seeing the heartbeat of the fetus in sonography)
Method of measurement
Pregnancy blood test and transvaginal ultrasound

Intervention groups

1

Description
Intervention group: The study subjects will be all patients who refer to Infertility & IVF center (Ayatollah Taleghani Hospital) from April 1402 to October 1402 and meet the inclusion criteria and DOR and their last IVF cycle was last year and they did not get pregnant and are candidates for another IVF cycle. Briefing sessions of the patient will be held with his spouse in the consultation room of Ayatollah Hospital, and at the end all the patient's questions will be answered. Finally, an informed consent form will be given to the patient and his wife, and the treatment method will be explained in writing. In this method, very small stem cells obtained from peripheral blood are injected vaginally into the ovaries on both sides after separation from the blood by centrifugation and apheresis. After 3 months, the patient undergoes IVF according to her treatment cycle.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
infertility & IVF center of Ayatollah Taleghani Hospital
Full name of responsible person
Hajar Abbasi
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next to Shahid Beheshti University of Medical Sciences., Shahid Arabi St., Yemen St., Shahid Chamran Highway., Tehran., IRAN
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Fax
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
دکتر افشین زرقی
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No.2, Arabi St., Yemen St., Chamran Highway., Shahid Beheshti University of Medical Sciences,, Tehran., Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
60
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
Shahid Beheshti University of Medical Sciences
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Hajar Abbasi
Position
assistant professor
Latest degree
Specialist
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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