

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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 considered.

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

Country

Iran (Islamic Republic of)

Phone

+98 21 7758 2543

Email address

dr_abbasi65@sbmu.ac.ir

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

Street address

next to Shahid Beheshti University of Medical Sciences., Shahid Arabi St., Yemen St., Shahid Chamran Highway., Tehran., IRAN

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Fax

Email

taleghanihospital@sbmu.ac.ir

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 زرقي

Street address

No.2, Arabi St., Yemen St., Chamran Highway., Shahid Beheshti University of Medical Sciences., Tehran., Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 3422 0879

Email

Mpajouhesh@sbmu.ac.ir

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

Full name of responsible person

Hajar Abbasi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No.11, Baharestan 9th Ave., Pasdaran Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1958713414

Phone

+98 21 2259 0592

Email

haabbasi65@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hajar Abbasi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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1985711151

Phone

+98 21 2259 0592

Email

haabbasi65@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hajar Abbasi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

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1958713414

Phone

+98 21 2259 0592

Email

haabbasi65@gmail.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