Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Set up of new stem cell therapy method for infertile women with diminished ovarian reserve (DOR) by using autologous menstrual blood-derived stem cells and plasma rich platelet (PRP)

Protocol summary

Study aim
Evaluation the effect of mesenchymal stem cells derived from menstrual blood and autologous platelet-rich plasma (PRP) on ovarian reserves and pregnancy

Design
Clinical trial with a control group, with parallel groups, without blinding, randomized, phase1,2 on 40 patients. The selection of the group type for each person through random allocation 2 statistical software.

Settings and conduct
1. Isolation and culture of mesenchymal stem cells from menstrual blood of DOR patients in Clean room of Sinai Mehr Fajr Laboratory in Sari 2. Flow cytometry 4. Preparation of PRP 5. Patient selection 6. Check the serum level of AMH, FSH, estradiol and AFC two weeks before and after injection. Registration of embryo quality and pregnancy success rate after injection in Imam Khomeini Hospital, Sari

Participants/Inclusion and exclusion criteria
Inclusion criteria : 20 to 45 years old with DOR, history of infertility for more than one year, rejection of at least one IVF, AFC of two ovaries less than 7 or serum level of AMH less than 1.1 ng/mL, with few egg count or low quality embryos in IVF cycle. Absence of ovulation or amenorrhea (at least three months). Exclusion criteria: Pregnancy, IgA deficiency, secondary ovarian failure caused by sex chromosomes, use of anticoagulants, history of mental illnesses with drug addiction, surgery leading to pelvic adhesions, malignancy or chronic pelvic pain, infertility due to severe male factor, abnormal uterine shape and endometrium caused by abscess.

Intervention groups
4 intervention groups.One group is injected with autologous menstrual blood-derived stem cells, the other group is injected with autologous PRP, the next group is injected with both stem cells and PRP, and nothing is injected into the control group.

Main outcome variables
AMH; AFC; FSH; Estradiol; Embryo quality; Pregnancy success rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231230060569N1**
Registration date: **2024-04-01, 1403/01/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-01, 1403/01/13**
Update count: **0**

Registration date
2024-04-01, 1403/01/13

Registrant information
Name
Manizheh Habibpour
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-01-21, 1402/11/01
Expected recruitment end date
2024-07-21, 1403/04/31
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Set up of new stem cell therapy method for infertile women with diminished ovarian reserve (DOR) by using autologous menstrual blood-derived stem cells and plasma rich platelet (PRP)

Public title
Stem cell therapy for infertile women with diminished ovarian reserve (DOR)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Female 20 to 45 years old with DOR having a history of infertility for more than a year Rejecting IVF at least once The total number of antral follicles is less than 7 in two ovaries or the serum level of Anti Müllerin hormone is less than 1.1 ng/ml. Having a low egg count or low-quality embryos in an IVF cycle Absence of ovulation or amenorrhea that did not occur for at least three months before entering the study.
Exclusion criteria:
Pregnant people IgA deficiency (before or now) Secondary ovarian failure caused by sex chromosomes. Taking anticoagulants History of mental illnesses with drug addiction Surgery leading to pelvic adhesions. Malignancy or chronic pelvic pain Infertility caused by strong male factor. Dissatisfaction with the intervention Abnormal uterine shape and endometrium caused by abscess.
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
To allocate the samples to each group, the random block method will be used. For this purpose, patients will receive number 1 to 40 according to their arrival. The randomization unit will be individually and by number with blocks of 4 people. The selection of the group type for each person will be done through random allocation 2 statistical software. In order to make a random sequence, A, B, C, D codes will be generated from the software, and each code will be considered for one group. Finally, the codes will be placed in the sealed envelope and the number of each patient will be written on the envelope. As each patient enters, the doctor will open the envelope and apply the desired treatment.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The output of this project is the acquisition of technical knowledge to create a new cell therapy protocol for DOR patients, and finally, after the evaluation of clinical trials, it can enter the health market as a knowledge-based and technological product or service.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
No. 94, Dolat Ave., Pasdaran Blvd., Sari Town
City
Sari
Province
Mazandaran
Postal code
4814979583
Approval date
2023-01-04, 1401/10/14
Ethics committee reference number
IR.MAZUMS.REC.1401.476

Health conditions studied

1

Description of health condition studied
Diminished Ovarian Reserve(DOR)
ICD-10 code
E28.9
ICD-10 code description
Ovarian dysfunction, unspecified

Primary outcomes

1

Description
Anti Mullerian hormone
Timepoint
2 weeks before and after injection
Method of measurement
ELISA KIT

2

Description
Antral Follicle Count(AFC)
Timepoint
2 weeks before and after injection
Method of measurement
ELISA KIT

3

Description
Estradiol
Timepoint
2 weeks before and after injection
Method of measurement
ELISA KIT

4

Description
FSH
Timepoint
2 weeks before and after injection
Method of measurement
ELISA KIT

Secondary outcomes

1

Description
Pregnancy success rate
Timepoint
after delivery
Method of measurement
Observation

2

Description
Embryo quality
Timepoint
3 days after conception
Method of measurement
Microscope

Intervention groups

1

Description
Intervention group: Injection of 1 ml of autologous PRP in 1 step into the ovaries of DOR patients under mild anesthesia with ultrasound guidance
Category
Treatment - Other

2

Description
Intervention group: Injection of 1 ml of stem cells derived from autologous menstrual blood in 1 step into the ovaries of DOR patients under mild anesthesia with ultrasound guidance
Category
Treatment - Other

3

Description
Intervention group: Simultaneous injection of 1 ml of autologous PRP and stem cells derived from autologous menstrual blood in 1 step into the ovaries of DOR patients under mild anesthesia with ultrasound guidance
Category
Treatment - Other

4

Description
Control group: No injection
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Marzieh Zamaniyan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram Ebrahimnejad
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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
Mazandaran University of Medical Sciences

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
Mazandaran University of Medical Sciences
Full name of responsible person
Manizheh Habibpour
Position
Associate professor
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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