Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of autologous Platelet-Rich Plasma and Condition Medium of mesenchymal stem cells derived from the umbilical cord on the serum level of Anti Mullerian Hormone in infertile women with Diminished Ovarian Reserve

Protocol summary

Study aim
Investigating the effectiveness of autologous Platelet-Rich Plasma (PRP) and Condition Medium of mesenchymal stem cells derived from the umbilical cord on the serum level of Anti Mullerian Hormone (AMH)

Design
Clinical trial with a control group, with parallel groups, no blinding, randomized, phase1,2 on 44 patients.

Settings and conduct
1. Patient identification 2. Preparation of umbilical cord from a newborn in Imam Khomeini Hospital, Sari 3. Preparation of Condition Medium of mesenchymal stem cells derived from the umbilical cord in the clean room of Sina Mehr Fajr Laboratory, Sari 4. Preparation of PRP in Imam Khomeini Hospital, Sari 5. Injection into the ovaries in the operating room of Imam Khomeini Hospital, Sari 6. Examination of serum AMH and AFC levels of patients before injection and 2, 6 and 14 weeks after injection

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women between 20 and 45 years of age, infertility for more than one year, having poor or diminished ovarian reserve, and one of the poor ovarian response criteria, which are: Total AFC in both ovaries 7 or less on vaginal ultrasound, AMH less than 1.1 ng/ml, history of IVF with 3 or less eggs, signing informed consent form. Exclusion criteria: Pregnancy, history of IgA deficiency or currently, surgery leading to pelvic adhesions, taking anticoagulant drugs, mental illness with drug dependence, chronic malignancies or chronic pelvic pain, severe male factor infertility, drug addiction, endometriosis and abnormal uterine shape observed on hysterosalpingography, failure to sign the informed consent form.

Intervention groups
4 intervention groups: One group is injected with only autologous PRP, the other group with only Condition Medium, the next group with Condition Medium and PRP concurrently, and no injection for the control group.

Main outcome variables
Anti Mullerian Hormone, Antral Follicle Count

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231230060569N2**
Registration date: **2024-12-30, 1403/10/10**
Registration timing: **prospective**

Last update: **2024-12-30, 1403/10/10**
Update count: **0**

Registration date
2024-12-30, 1403/10/10

Registrant information

Name
Manizheh Habibpour

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
2025-01-20, 1403/11/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of autologous Platelet-Rich Plasma and Condition Medium of mesenchymal stem cells derived from the umbilical cord on the serum level of Anti Mullerian Hormone in infertile women with Diminished Ovarian Reserve

Public title

Cell therapy in infertile women with Diminished Ovarian Reserve

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women between 20 and 45 years old Having poor or diminished ovarian reserve and having one of the criteria for poor ovarian response, which are: total number of Antral Follicles Count in both ovaries 7 or less on vaginal ultrasound, AMH less than 1.1 ng/ml, history of IVF with 3 or fewer eggs Reading and signing the informed consent form

Exclusion criteria:

Pregnancy History or current IgA deficiency History of surgery leading to pelvic adhesions Taking anticoagulant medications Mental illness with dependence on drug use Chronic malignancies or chronic pelvic pain Infertility due to severe male factor Drug addiction Endometriosis and abnormal uterine shape observed in hysterosalpingogram Failure to sign the informed consent form

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: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate samples to each group, the random block method will be used. For this purpose, patients will receive numbers 1 to 44 according to their arrival. The randomization unit will be individual and by number with blocks of 4 people. The selection of the type of group for each individual will be done through the statistical software 2 allocation random. To create a random sequence, the software will generate codes A, B, C, D, and each code will be considered for one group. Finally, the codes will be placed in a sealed envelope and the number of each patient will be written on the envelope. In the order of each patient's arrival, 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 Kerman University of Medical Sciences

Street address

Somayeh Intersection (Tahmaseb Abad), Beginning of Jihad Boulevard, Beginning of Ibn Sina Street

City

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Province

Kerman

Postal code

7616913555

Approval date

2024-11-25, 1403/09/05

Ethics committee reference number

IR.KMU.REC.1403.396

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

before injection and 2, 6 and 14 weeks after injection

Method of measurement

ELISA KIT

2

Description
Antral Follicle Count(AFC)
Timepoint
before injection and 2, 6 and 14 weeks after injection
Method of measurement
Vaginal ultrasound

Secondary outcomes

empty

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 Condition Medium of mesenchymal stem cells derived from umbilical cord 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 Condition Medium of mesenchymal stem cells derived from umbilical cord in 1 stage 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
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Full name of responsible person
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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
Kerman University of Medical Sciences
Proportion provided by this source
1
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
Student

Latest degree
Master

Other areas of specialty/work
Hematology

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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