Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of folliculogenesis in poor responds women after intrauterine injection of autologous platelet-rich plasma

Protocol summary

Study aim

Evaluation of folliculogenesis in poor responds women after intrauterine injection of autologous platelet-rich plasma

Design

Control group: A group of POR (Poor ovarian reserve) women who undergo follicular puncture without any treatment. Treatment group: A group of POR (Poor ovarian reserve) women undergoing ovarian PRP (Platelet-Rich Plasma) injection. This study is performed on 32 patients. Patients who meet the inclusion criteria are randomly divided into two groups of 16 using random block allocation with blocks of 4 and 6.

Settings and conduct

Sample collection is performed in Nekouei, Forqani Hospital, Reyhaneh Infertility center. Patients with inclusion criteria are randomly divided into two groups of 16 using random block allocation with blocks of 4 and 6.

Participants/Inclusion and exclusion criteria

POR participants must have a history of at least two of these: previous IVF attempts to recover less than three eggs or an abnormal ovarian reserve test involving less than five AFCs (Antral follicle count). Anemia, thrombophilic disorders, current cancer diagnosis or medical history of cancer

Intervention groups

patients with random block allocation will be assigned to intervention and control groups. Block size 4 will be considered. So we have six quadruple blocks consisting of AABB, ABAB, BBAA, BABA, ABBA, BAAB. The selection of each block will also be random and will be done using dice. For example, if the number 3 is rolled in a dice, the BBAA block is considered, so the first two patients are assigned to treatment B and the next two patients to treatment A.

Main outcome variables

Evaluation of transcript expression of genes involved in folliculogenesis shortly before treatment and after Platelet-Rich Plasma treatment Evaluation of expression

The rate of puberty and number of eggs and the quality of fetuses and spontaneous pregnancies will be compared.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220510054808N1**
Registration date: **2022-05-15, 1401/02/25**
Registration timing: **prospective**

Last update: **2022-05-15, 1401/02/25**
Update count: **0**

Registration date

2022-05-15, 1401/02/25

Registrant information

Name

Hoora Amoozegar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3721 1061

Email address

hamoozegar@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-26, 1401/03/05

Expected recruitment end date

2023-01-25, 1401/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of folliculogenesis in poor responds women after intrauterine injection of autologous platelet-rich plasma

Public title

Evaluation of folliculogenesis in poor responds women after intrauterine injection of autologous platelet-rich plasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

previous IVF (In vitro fertilisation) that resulted in the recovery of less than three eggs or an abnormal ovarian reserve test involving less than five AFCs (Antral follicle count) All women have a regular menstrual cycle. the level of follicles or AMH (Antimullerian Hormone) should be less than 1.1 ng / ml. those under 40 years of age.

Exclusion criteria:

Autoimmune disorders, sexually transmitted diseases, infectious diseases, infertility / tubal factor tube obstruction, chronic inflammatory diseases, endometriosis, chronic endometritis, and endocrine disorders such as thyroid dysfunction. anemia, thrombophilic disorders, current cancer diagnosis, or medical history of cancer

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the selection of the statistical population will be made available. And patients with random block allocation will be assigned to intervention and control groups. Block size 4 will be considered. So we have six quadruple blocks consisting of AABB, ABAB, BBAA, BABA, ABBA, BAAB. The selection of each block will also be random and will be done using dice. For example, if the number 3 is rolled in a dice, the BBAA block is considered, so the first two patients are assigned to treatment B and the next two patients to treatment A.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of qom University of Medical Sciences

Street address

Nekouei Hedayati Forghani Educational and Medical Center, Next to Mirzai Qomi Square, Azar street, Qom.

City

qom

Province

Ghoum

Postal code

3715873355

Approval date

2022-05-10, 1401/02/20

Ethics committee reference number

IR.MUQ.REC.1401.009

Health conditions studied

1

Description of health condition studied

Patients with poor ovarian response

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Platelet-enriched plasma cell count

Timepoint

After plasma preparation

Method of measurement

With cell counting machine

Secondary outcomes

1

Description

Expression of folliculogenesis genes

Timepoint

After collecting granulosa cells on the day of oocyte someone both the control group and the treated group

Method of measurement

Real time PCR

2

Description

Hormone secretion levels

Timepoint
At monthly intervals after the puncture and before the puncture
Method of measurement
Immunoassay

3

Description
Antral follicle count
Timepoint
At monthly intervals after the puncture and before the puncture
Method of measurement
sonography

4

Description
The quality of oocytes
Timepoint
after puncture
Method of measurement
with stereomicroscope

5

Description
oocyte and embryo quality
Timepoint
after puncture
Method of measurement
With a stereomicroscope

6

Description
Spontaneous fertility
Timepoint
14 days after embryo transfer
Method of measurement
Pregnancy test and sonography

Intervention groups

1

Description
Control group: A group of poor ovarian reserve women who undergo follicular puncture without any treatment
Category
Treatment - Drugs

2

Description
Intervention group: A group of poor ovarian reserve women undergoing ovarian PRP injection. Platelet-Rich Plasma (PRP) is administered to poor ovarian reserve women at the time of egg retrieval. PRP preparation is performed immediately after blood sample collection. Approximately 40 ml of the patient's peripheral blood is required to produce the required volume of PRP. The initial concentration of platelets in the peripheral blood is approximately 250,000 platelets per liter. The target platelet concentration in PRP was approximately 1,000,000 platelets per liter. According to our protocol, the prepared PRP can be stored at 4 ° C for one hour if needed. However, in the vast majority of participants, intrauterine injection of PRP is given immediately after preparation.Injections of both ovaries are seen through transvaginal ultrasound monitoring and are injected intra-medially at several sites using a single-lumen gauge needle 17. This technique involves penetrating the center of each ovary and then gradually injecting 3 ml of activated PRP into each ovary through a syringe connected to a transvaginal probe transducer.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Nekuei Hedayati Forqani Hospital
Full name of responsible person
Hoora Amoozegar
Street address
Nekouei Hedayati Forghani Educational and Medical Center, Next to Mirzai Qomi Square, Azar Street, Qom
City
qom
Province
Ghoum
Postal code
3715873355
Phone
+98 25 3721 1061
Email
hamoozegar@muq.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Alireza Koohpaei
Street address
No. 83, Lotfi Shahid Alley, Jahade Daneshghahi Street, Safashahr St,Qom
City
Qom
Province
Ghoum
Postal code
93456-37169
Phone
+98 25 3285 4011
Email
koohpaei19@yahoo.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Fatemeh Asgari
Position
Embryologist
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Nekuei Hedayati Forghani Educational and Medical Center ,next to Mirzai Qomi Square, Azar street, Qom
City
Qom
Province
Ghoum
Postal code
37158 73355
Phone
+98 25 3711 8428
Email
faasgsri@muq.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Fatemeh Asgari
Position
embryologist
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Nekuei Hedayati Forghani Educational and Medical Center ,next to Mirzai Qomi Square, Azar Street, Qom
City
Qom
Province
Ghoum
Postal code
37158 73355
Phone
+98 25 3711 8428
Email
faasgari@muq.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Fatemeh Asgari
Position
embryologist
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Nekuei Hedayati Forghani Educational and Medical Center ,next to Mirzai Qomi Square, Azar street, Qom
City
Qom
Province
Ghoum
Postal code
37158 73355
Phone
+98 25 3711 8428
Email
faasgari@muq.ac.ir

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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available