Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of platelet-rich plasma injection in the ovary on the number of oocytes; Oocyte quality and antimullerian hormone in cases of poor ovarian Responses.

Protocol summary

Study aim
Evaluation of the effect of PRP on ovarian function in patients with poor ovarian response.

Design
A non-randomized clinical trial with Control group; In parallel, Phase 4 will be performed on 44 infertile women with ovarian poor response and IVF candidates.

Settings and conduct
Infertile women referring to Valiasr Infertility Clinic of Imam Khomeini Hospital Complex of Tehran University of Medical Sciences will be selected in two groups of intervention (A) and control (B) with non-random conditions. In all patients, ovarian stimulation is initiated according to the antagonist protocol and in the intervention group, immediately after the follicle reaches 17 mm, 2 cc of enriched platelet (PRP) is injected into each ovary under anesthesia, and then the steps IVF is performed. PRP is not performed in the control group and they receive routine ovarian stimulation treatments.

Participants/Inclusion and exclusion criteria
Infertile women with poor ovarian function; Antimullerian hormone between 0.5-1.1 and the presence of at least ten million sperm with 3% of normal morphology are included in the study. Underlying diseases; Chromosomal abnormalities and hemoglobin less than 11 g / dL are not included in the study.

Intervention groups
Intervention group: After stimulation of the ovary and immediately after the follicle reaches 17 mm, 2 cc of enriched platelet (PRP) is injected into each ovary under anesthesia at the same time as the puncture. In the control group, PRP is not performed and routine ovarian stimulation is performed.

Main outcome variables
The number of eggs grown and the level of the antimullerian hormone are the main outcomes and chemical pregnancy and clinical pregnancy are the secondary outcomes of the study.

General information

Reason for update
Setting primary and secondary outcomes; Set the exact study time; Set study inclusion and exclusion criteria.

Acronym

IRCT registration information
IRCT registration number: **IRCT20141217020351N11**
Registration date: **2020-11-25, 1399/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-01, 1400/10/11**
Update count: **2**

Registration date
2020-11-25, 1399/09/05

Registrant information

Name
Ensieh Shahrogh Tehraninejad

Name of organization / entity
Tehran University Of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-01, 1399/07/10

Expected recruitment end date
2021-08-31, 1400/06/09

Actual recruitment start date

2020-10-01, 1399/07/10

Actual recruitment end date

2021-04-19, 1400/01/30

Trial completion date

2021-06-20, 1400/03/30

Scientific title

The effect of platelet-rich plasma injection in the ovary on the number of oocytes; Oocyte quality and antimullerian hormone in cases of poor ovarian Responses.

Public title

The effect of plasma injection in the ovary on the number of Follicle and oocytes, the quality of oocytes, and Anti Mullerian hormone in cases of poor ovarian function.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The second cycle of embryo transfer Criteria for detecting poor ovarian function based on the Bologna criterion Age less than 45 years History of having at least three oocytes in the previous cycle AMH hormone less than 1.1 ng / ml BMI less than 30kg/m2 At least ten million sperm and three percent sperm with a normal morphology

Exclusion criteria:

Immunological diseases Hematological diseases Chromosomal or genetic disorder Uterine disorders Hemoglobin level less than 11 grams per deciliter Platelets less than one hundred and fifty thousand per cubic millimeter Systemic use of corticosteroids within two weeks before the procedure Hypothyroidism Respiratory tract infections Kidney failure Endometriosis Sub mucusal myoma Asherman Syndrome Pathology of the Fallopian tubes (Hydrosalpinx) Endocrine diseases Endocrine diseases Allergic reactions The dissatisfaction of the patient to continue treatment No contraindications for pregnancy

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **44**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex ,Keshavarz Blvd.

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Tehran

Postal code

1419733141

Approval date

2020-09-30, 1399/07/09

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.271

Health conditions studied

1

Description of health condition studied

Female Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Number of oocyte

Timepoint

Two months after the PRP

Method of measurement

Vaginal Sonography

2

Description

Antimullerian hormone

Timepoint

Two months after the PRP

Method of measurement

Blood Test

3

Description

The quality of oocyte

Timepoint

Two months after the PRP

Method of measurement
Vaginal Sonography

Secondary outcomes

1

Description
Number of obtained of embryo
Timepoint
Two months after the PRP
Method of measurement
Embryologist diagnosis

2

Description
The quality of resulted embryo
Timepoint
Two months after the PRP
Method of measurement
Embryologist diagnosis

3

Description
Chemical Pregnancy
Timepoint
Two weeks after the embryo transfer
Method of measurement
Blood Test

Intervention groups

1

Description
Intervention group:In all patients, ovarian stimulation is initiated according to the antagonist protocol and immediately after the follicle reaches 17 mm at the same time as oocyte removal; 2 cc of enriched platelet solution (PRP) is injected into each ovary under anesthesia and then IVF steps are performed.
Category
Treatment - Drugs

2

Description
Control group: In this group, PRP is not performed and only routine ovarian stimulation treatments are performed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali -Asr Infertility Clinic,Imam Khomeini Hospital Complex .,
Full name of responsible person
Ensieh Shahrokh Tehraninehad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Vice Chancellor for Research of Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Maryam Alsadat Razavi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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