

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Single blind clinical trial of Effects Of Autologus Platelet- Rich Plasma on Pregnancy Rate in ICSI cycles in Repeated Implantation Failure Patients.

Protocol summary

Summary

This research is designed to evaluate the effect of intrauterine injection of Platelet Rich Plasma (PRP) in Repeated Implantation Failure (RIF) patients. In a single blind randomized clinical trial, 60 patients between 20 till 41 years old who have repeated implantation failure (according to references) and now have planned for ICSI in Avicenna Infertility Clinic, randomized to two equal groups with computerized randomization. Antagonist type of ICSI cycle will be done for these patients who have at least 2 times unsuccessful good quality embryo transfer and have 10 million sperm with 3% normal morphology in their husbands' sperm analysis. Ovarian retrieval will be done after injection of ovarian hyper stimulating drugs for the patients. The intervention will be done If good quality embryos (grade A or B) form. In intervention group, PRP will be injected intra uterine through embryo transfer catheter 48 hours before embryo transfer. In control group, embryo transfer catheter will be inserted and removed without injection of anything 48 hours before embryo transfer. Chemical (2 weeks after embryo transfer) and clinical pregnancy rate (6 weeks after embryo transfer) and implantation rate will be compared in two different groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061034422N1**

Registration date: **2017-11-05, 1396/08/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-05, 1396/08/14

Registrant information

Name

Sheyda Jouhari

Name of organization / entity

Avicenna Research Center

Country

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Recruitment status

Recruitment complete

Funding source

Avicenna Research Institute

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Single blind clinical trial of Effects Of Autologus Platelet- Rich Plasma on Pregnancy Rate in ICSI cycles in Repeated Implantation Failure Patients.

Public title

Effects Of Autologus Platelet- Rich Plasma on Pregnancy Rate in Intra Cytoplasmic Sperm Injection (ICSI) cycles in Repeated Implantation Failure Patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients who have had at least two unsuccessful embryo transfer cycles (fresh or frozen embryo); At least 6 good quality embryos (grade A or B) were transferred in previous cycles; Semen count ≥ 10 millions, normal morphology $\geq 3\%$ in their husbands' semen analysis Exclusion criteria: Patients with immunologic disorders (abnormality in CD markers, Anti TG, Anti TPO, ds DNA, ANA); Hematologic disorder; Genetic diseases; Uterus disorders; Hb < 11 mg/dl and Platelet < 150000 /mm³; Systemic usage of corticosteroids during 14 days before use of PRP

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Avicenna Research Institute

Street address

Avicenna Research Institute, Shahid Beheshti University, Velenjak, Tehran

City

Tehran

Postal code

19615-1177

Approval date

2017-05-02, 1396/02/12

Ethics committee reference number

IR.ACECR.Avicenna.REC.1396.8

Health conditions studied**1****Description of health condition studied**

INFERTILITY- recurrent implantation failure

ICD-10 code

98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes**1****Description**

Chemical Pregnancy Rate

Timepoint

Two weeks after embryo transfer

Method of measurement

Blood Beta HCG

2**Description**

Clinical Pregnancy Rate

Timepoint

Six weeks after embryo transfer

Method of measurement

Sonography. If normal fetal heart rate will be seen in sonography

Secondary outcomes**1****Description**

Implantation Rate

Timepoint

Six weeks after embryo transfer

Method of measurement

Statistical method by (number of embryos transfer / number of pregnancy sacs in sonography 6 weeks after ET)

Intervention groups**1****Description**

In intervention group, PRP will be done for patient 48 hours before embryo transfer. For PRP, 8.5 cc of peripheral blood will be given and the number of platelet will be checked. Then the blood will be put in a space which has 2.5 cc special anti coagulant and centrifuged with 1200 rpm for 12 minutes. Then superior part of plasma will be separated and centrifuged with 3500 rpm for 6 minutes again. The platelet number will be checked again and if it becomes 4 to 5 times, 0.5 cc of this solution will be transferred into uterus cavity 48 hours before embryo transfer.

Category

Treatment - Other

2

Description

In control group, the embryo transfer catheter will be inserted for patient 48 hours before embryo transfer and will be removed without injection of anything.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Avicenna Infertility Clinic

Full name of responsible person

Sheyda Jouhari, Infertility Fellowship

Street address

No 97, Yakhchal St, Shariati St, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Avicenna Research Institute

Full name of responsible person

Dr Seyed Ali Azin

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Avicenna Research Institute, Shahid Beheshti University, Velenjak, Tehran

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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

Avicenna Research Institute

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Avicenna Infertility Clinic

Full name of responsible person

Sheyda Jouhari

Position

MD, Infertility Fellowship

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty