

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effectiveness of one time and two times PRP and non-performing PRP in three groups of women with at least two or more pregnancy failures in high-quality embryo transfer who are candidates for embryo freezing in the embryo transfer cycle

Protocol summary

Study aim

Evaluate the effectiveness of PRP on pregnancy rate and also compare the difference between doing it in one or two stages

Design

In this study, which will be conducted in parallel, 180 women randomized in a three-block method will be compared in three groups of 60 people, all groups will be referred twice for PRP, one on the 8th day. Menstruation and another 48 hours before the transfer

Settings and conduct

This study was performed in two hospitals, Zeinabieh and mother and child

Participants/Inclusion and exclusion criteria

- Having the consent to enter the study
- Age <40 years
- Body mass index (BMI) <30 kg / m²

Intervention groups

This study included three groups of 60 women with two or more recurrent implant failures. In the first group, as a control group, no PRP infusion was given and only an empty catheter was inserted into the uterine cavity. The other two groups are intervention groups, one of which is an empty catheter and the second PRP catheter is inserted into the uterine cavity and the other two catheters containing PRP are infused into the uterine cavity.

Main outcome variables

The consequence of the plan, pregnancy or non-pregnancy of patients following PRP infusion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211108052998N1**

Registration date: **2022-03-09, 1400/12/18**

Registration timing: **prospective**

Last update: **2022-03-09, 1400/12/18**

Update count: **0**

Registration date

2022-03-09, 1400/12/18

Registrant information

Name

Sedigheh Amooee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-25, 1401/01/05

Expected recruitment end date

2022-06-04, 1401/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of one time and two times PRP and non-performing PRP in three groups of women with at least two or more pregnancy failures in

high-quality embryo transfer who are candidates for embryo freezing in the embryo transfer cycle

Public title

The effect of Platelet rich plasma on pregnancy in patients with repeated implantation failure .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to enter the study Age <40 years Body mass index (BMI) <30 kg / m²

Exclusion criteria:

Existence of any uterine abnormalities (congenital or acquired) Existence of any uterine abnormalities (congenital or acquired) Uncontrolled hormonal disease (prolactinemia or thyroid disease) and endometriosis Blood diseases (hemoglobin <9.0 g / dl and platelet count <100,000 per microliter) Chromosomal defects in the patient or spouse Lack of quality blastocysts (Grade A or B according to embryological score) for transmission

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the three-block randomization method has been used. This study is performed in two hospitals: Hazrat Zeinab and Ghadir mother and child. Randomly and without informing the researcher and the assessment team and only with the knowledge of the clinical caregiver, people in both hospitals were randomized by three-block method and all three patients were divided into control and intervention one and intervention two groups, respectively. The assignment of individuals to study groups will be such that according to the list of attribution codes generated in the random assignment process, one of the three clients will be given a code that indicates which group each person belongs to. Due to the blinding of evaluators and researchers in this method of random allocation, we have tried to reduce the bias in the study to a minimum.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double blind and in which patients and researchers do not know the order of random distribution of patients and only the executor knows about it. Blood samples are taken from all patients in the same way to

prepare PRP. The patient's field of vision is limited by the barrier between the patient and the clinical caregiver. In the control group, which does not receive any PRP, like other patients, he lies on the bed and in both cases, only an empty catheter without PRP enters the patient's uterine cavity. In the second group, the catheter is emptied for the first time and the catheter containing PRP in the uterine cavity is infused in the second time. In the third group of patients, a catheter containing PRP is infused into the uterine cavity on both occasions.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz

City

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Province

Fars

Postal code

3478671946

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.SUMS.MED.REC.1400.0322

Health conditions studied

1

Description of health condition studied

Does not apply. Because this study is not about diseases.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The study has only one outcome and the end result is a pregnancy test. At the end of the cycle, pregnancy is determined by laboratory evaluation of serum β -HCG and the presence of fetal heartbeat on transvaginal ultrasound 2 weeks and 5 weeks after embryo transfer, respectively

Timepoint

evaluation of serum β -HCG and the presence of fetal heartbeat on transvaginal ultrasound 2 weeks and 5 weeks after embryo transfer

Method of measurement

Transvaginal sonography

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group is the group in which PRP is infused only once for the patient. The initial preparation steps of the control and intervention groups are performed in the same way. For all patients in all three groups, an embryo transfer cycle will be performed by freezing and hormone therapy to prepare the endometrium. For this purpose, estradiol valerate (manufactured by Abu Reihan Company, Tehran, Iran) will be started at a dose of 6 mg on the 3rd day of menstruation and will increase to 8 mg per day if the endometrial thickness does not reach at least 8 mm. During this cycle, when the endometrial thickness is greater than 8 mm, a progesterone suppository (manufactured by Actavis, UK) is started at a dose of 400 mg twice daily for the patient. Quality blastocysts (Grade A or B according to embryological score) will be used for transmission in all patients. All fetal transfers will be performed under ultrasound and by an experienced obstetrician with an infertility fellowship. Embryo transfer is based on the guidelines of the American Reproductive Medicine Association (2 or 3 embryos per patient). Estradiol valerate and progesterone suppositories continue for two weeks after embryo transfer, and if serum β -HCG is positive, these hormones will continue until the 12th week of pregnancy. In this group, PRP infusion is performed only 48 hours before the transfer, and on the 8th day of menstruation, only an empty catheter without PRP enters the uterine cavity.

Category

Other

2

Description

Intervention group: Intervention group 2. Group in which two PRP infusions are performed on 8 menstrual days and 48 hours before transfer.

Category

Other

3

Description

Control group: The control group is the group in which an empty catheter enters the uterine cavity on both occasions and no PRP infusion is performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeinabiyyeh Hospital Fertility Clinic

Full name of responsible person

Sedigheh Amooee

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Department of Obstetrics and Gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

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Sponsors / Funding sources

1

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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

Shiraz 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

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Person responsible for general inquiries

Contact

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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