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)

Phone
+98 71 3233 2365

Email address
sedighehamooee@gmail.com

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
Shiraz
Province
Fars
Postal code
3478671946
Approval date
2021-09-19, 1400/06/28
Ethics committee reference number
IR.SUMS.MED.REC.۱۴۰۰.۳۲۴

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

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

City
Shiraz

Province
Fars

Postal code
07134814336

Phone
+98 71 3233 2365

Email
Sedighehamooee@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Abbas Rezaianzadeh

Street address
Shiraz University of Medical Sciences, Zand St, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
07134814336

Phone
+98 71 3230 5410

Email
rezaiana@sums.ac.ir

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

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zeinab Shahryari

Position

Resident of obstetrics and gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3233 2365

Email

Zeinabsh3576@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zeinab Shahryari

Position

Resident of obstetrics and gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3233 2365

Email

Zeinabsh3576@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shahryari Zeinab

Position

Resident of obstetrics and gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

7

Email

Zeinabsh3576@gmail.com

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