Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of intrauterine infusion of platelet_rich plasma on pregnancy outcome in patients with repeated implantation failure.

Protocol summary

Study aim
To evaluate the effectiveness of platelet-rich plasma in improvement of pregnancy and implantation rate in women with history of repeated implantation failure.

Design
Clinical trial with total of 120 eligible women that randomly assigned into two equal parallel groups (intervention and control)through Balanced Block Randomization. (Block size=4).

Settings and conduct
After endometrial preparation for embryo transfer in both groups, In intervention group,48 hours before embryo transfer (ET), 20 ml of peripheral venous blood will be obtained by syringe pre-filled with 2ml of anticoagulant solution,and then will be centrifuged immediately at 170 g for 10 minutes to separate red blood cells.this plasma will be re_centrifuged at 340 g for 5 minutes to obtain platelet-rich plasma (PRP), that contained platelet 4-5 times more than peripheral blood. 0.5ml of PRP will be infused into the uterine cavity with IUI catheter and after 48 hours, ET will be done. In control group, ET will be done without intrauterine infusion of PRP. After 2 weeks of ET, serum Beta_human chorionic Gonadotropin (β HCG) will be measured in all patients. This research will be done at Infertility Department Of Shariati Hospital, Tehran, Iran

Participants/Inclusion and exclusion criteria
Infertile 20-40 years old women that failed to conceive after three or more embryo transfer and have at least one frozen good - quality blastocyst- stage embryo,body mass index below 30 kg/m2, without Genetic, Chromosomal, Uterine, Immunologic, Hormonal and Hematologic disorders.

Intervention groups
In intervention group,48 hours before embryo transfer, 0.5ml of platelet-rich plasma will be infused into the uterine cavity with IUI catheter. In control group embryo transfer undergoing without intrauterine infusion of platelet-rich plasma.

Main outcome variables
Clinical Pregnancy Implantation Rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190503043454N1**
Registration date: **2019-07-06, 1398/04/15**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-06, 1398/04/15**
Update count: **0**

Registration date
2019-07-06, 1398/04/15

Registrant information
Name
Parvaneh Lak
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2249 8504
Email address
lakparvaneh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2019-08-23, 1398/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of intrauterine infusion of platelet_rich plasma on pregnancy outcome in patients with repeated implantation failure.

Public title
Efficacy of platelet_rich plasma on embryo implantation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women between 20 -40 years old History of at least 3 or more failure in embryo transfer Have at least one frozen Blastocyst - stage embryo Body Mass Index below 30 kg/m2
Exclusion criteria:
Congenital or acquire uterine abnormalities Genetic or chromosomal abnormalities Immunologic disorders Hematologic disorders Hormonal disorders
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Balanced Block Randomization (Block size=4): We prepare four balls,two A and two B.for first patient ,a nurse who does not know our plan for both A and B groups, selects one ball randomly from basket.for next patient this selection were done through remaining three balls.for third patient from remaining two balls and the last ball for the fourth patient, and then another block was selected.therefore our blocks show one of these pattern. (BAAB) (BABA) (ABBA) (BBAA) (ABAB) (AABB)
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
Room 605, Floor 6 , Central Building Of Tehran University Of Medical Science., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2017-08-09, 1396/05/18
Ethics committee reference number
86388

Health conditions studied

1

Description of health condition studied
Repeated Implantation Failure
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Clinical Pregnancy
Timepoint
4 weeks after embryo transfer
Method of measurement
To detect gestational sac with Fetal Heartbeat by Trans Vaginal Ultrasound.

2

Description
The Implantation Rate
Timepoint
Four weeks after the embryo transfer
Method of measurement
The ratio of gestational sac determination on trans vaginal ultra Sonography to the number of transferred embryos.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:48 hours before embryo transfer (ET), 20 ml of peripheral venous blood will be obtained by syringe pre-filled with 2ml of Acid Citrate A anticoagulant solution(Royagen),and then will be centrifuged

immediately at 170 g for 10 minutes to separate red blood cells.this plasma will be re_centrifuged at 340 g for 5 minutes to obtain platelet-rich plasma (PRP), that contained platelet 4-5 times more than peripheral blood. 0.5ml of PRP will be infused into the uterine cavity with IUI catheter and after 48 hours, ET will be done with IUI catheter(Takwin,Iran).

Category

Treatment - Other

2

Description

Control group: ET will be done with IUI catheter without intrauterine infusion of PRP.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Lak Parvaneh

Street address

Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Fax

+98 21 8863 3039

Email

shariatihosp@tums.ac.ir

Web page address

http://shariati.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

TUMS Vice Chancellor for Research., Tehran University of Medical Sciences .,Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3619

Fax

+98 21 8163 3611

Email

rmo@tums.ac.ir

Web page address

http://vcr.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Parvaneh Lak

Position

Fellowship of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 2, Sohani Ave., Mohammadi far St., Ghaem Town., Artesh High way., Tehran., Iran

City

Tehran

Province

Tehran

Postal code

1955848979

Phone

+98 21 2249 8504

Fax

Email

lakparvaneh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parvaneh Lak

Position

Fellowship of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 2, Sohani Ave., Mohammadi far St., Ghaem Town., Artesh High way., Tehran., Iran

City

Tehran

Province

Tehran

Postal code

1955848979

Phone

+98 21 2249 8504

Fax

Email

lakparvaneh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parvaneh Lak

Position

Fellowship of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 2, Sohani Ave., Mohammadi far St., Ghaem Town., Artesh High way., Tehran., Iran

City

Tehran

Province

Tehran

Postal code

1955848979

Phone

+98 21 2249 8504

Fax

Email

lakparvaneh@yahoo.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