

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Effect of platelet rich plasma (PRP) on improving pregnancy outcome in recurrent pregnancy loss patients a randomized clinical trial pilot study

Protocol summary

Study aim

Effect of platelet rich plasma (PRP) on live birth rate

Design

This double-blind, phase 2, randomized controlled clinical trial will perform in 50 patients with recurrent pregnancy loss and undergoing IVF treatment at Taleghani Hospital. Participants will be assigned to one of the control or intervention groups and each group will be 25 people.

Settings and conduct

This clinical trial will be performed in Infertility and IVF unit, Taleghani hospital. Fifty infertile patients with recurrent pregnancy loss will be recruited into study in two groups according to randomization method. Consent form will be taken from participants after awareness of them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women under 40 years old, 30>BMI, and at least two previous pregnancy loss. exclusion criteria: Immunological or hematological disorders, Antiphospholipid antibody syndrome, hormonal or chromosomal abnormalities, and congenital or acquired uterus disorders.

Intervention groups

In intervention group, intrauterine administration of PRP will be performed 48 hours before embryo transfer. Autologous PRP will be prepared during a 2-step procedure. Prepared PRP (5 CC) will be inoculated into uterus. Hormonal therapy will continue until two weeks after embryo transfer.

Main outcome variables

Pregnancy and live birth rates

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160722029027N9**

Registration date: **2019-12-04, 1398/09/13**

Registration timing: **retrospective**

Last update: **2019-12-04, 1398/09/13**

Update count: **0**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

Leila Nazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2271 8000

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of platelet rich plasma (PRP) on improving pregnancy outcome in recurrent pregnancy loss patients a randomized clinical trial pilot study

Public title

Effect of platelet rich plasma (PRP) improving pregnancy

outcome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Women under 40 years 30>BMI At least two pregnancy loss
Exclusion criteria:
 Immunologic disorder Anti phospholipid syndrome
 Hormonal disturbance Chromosomal disorder Congenital and acquired uterine disorder Hematological disturbance

Age
To 40 years old

Gender
Female

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by generating random numbers in Excel software. 1. In a column of Excel we enter 25 samples in each group. 2. In the next column we generate random numbers using the following command: RAND () 3. After sorting the generated random numbers, a random list will be generated according to which people will be assigned to two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blindness will be such that the patient will not know what treatment she will receive. Also, the researcher who records the results will not be aware of the type of treatment applied to the patient.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yaman St, Chamran highway

City

Tehran
Province
 Tehran
Postal code
 1983969411

Approval date

2019-10-01, 1398/07/09

Ethics committee reference number

IR.SBMU.REC.1398.079

Health conditions studied

1

Description of health condition studied

Noninflammatory disorders of female genital tract

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

5-7 weeks of gestation

Method of measurement

Ultrasonography

2

Description

Ongoing pregnancy

Timepoint

20 weeks of gestation

Method of measurement

Ultrasonography

3

Description

Live birth

Timepoint

9 months after embryo transfer

Method of measurement

Visualization

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Initiation of ovarian stimulation will start on day 3 of the menstrual cycle. Follicular monitoring will perform using serial ultrasonography. When the diameter of follicles reached approximately 14 mm, the GnRH antagonist will start. When at least three

follicles >17 mm diameter visualizes in the ovaries, ovulation trigger will carry out using 10000 IU of human chorionic gonadotropin (hCG). The oocytes will aspirate from the ovaries 36 hours later. After intra-cytoplasmic sperm injection, intrauterine administration of platelet rich plasma (PRP) will be performed 48 hours before embryo transfer. Autologous PRP will be prepared during the 2-step procedure. Prepared PRP (5 CC) will be inoculated into the uterus. Finally, blastocyst embryos will transfer to the uterus.

Category

Treatment - Other

2

Description

Control group: Initiation of ovarian stimulation will start on day 3 of the menstrual cycle. Follicular monitoring will perform using serial ultrasonography. When the diameter of follicles reached approximately 14 mm, the GnRH antagonist will start. When at least three follicles >17 mm diameter visualizes in the ovaries, ovulation trigger will carry out using 10000 IU of human chorionic gonadotropin (hCG). The oocytes will aspirate from the ovaries 36 hours later. After intra-cytoplasmic sperm injection, blastocyst embryos will transfer to the uterus.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility and IVF unit of Talghani hospital

Full name of responsible person

Leila Nazari

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Yaman St, Velenjak, Chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Teibeh Hashemi

Position

Fellowship of infertility

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only information about the main outcome can be shared.

When the data will become available and for how long

Without restriction

To whom data/document is available

All researchers

Under which criteria data/document could be used

With permission from the responsible author

From where data/document is obtainable

Email to the responsible author

What processes are involved for a request to access data/document

Email to the responsible author

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hashemi Teibeh

Position

Fellowship of infertility

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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