Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 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
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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

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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
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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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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