

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

effect of intrauterine infusion of autologous platelet-rich plasma (PRP) on endometrial thickness and pregnancy rate as secondary endpoint in FET cycles.

Protocol summary

Summary

Overall Objective: Evaluation of the effect of intrauterine infusion of platelet-rich plasma (PRP) on endometrial thickness in infertile women that have insufficient endometrial thickness in frozen embryo transfer cycles. Patients treated for frozen embryo transfer cycles after intrauterine infusion of PRP. The endometrial thickness in patients treated for frozen embryo transfer cycles without intrauterine infusion of PRP. Compare the endometrial thickness in patients treated for frozen embryo transfer cycles after intrauterine infusion of PRP and control group pregnancy rate in patients treated for frozen embryo transfer cycles after intrauterine infusion of PRP pregnancy rate in patients treated for frozen embryo transfer cycles without intrauterine infusion of PRP. Compare pregnancy rate in patients treated for frozen embryo transfer cycles after intrauterine infusion of PRP and group control. Material and Method: In this study 100 infertile patients who have come to infertility clinic of mother and child hospital for transfer frozen embryo that have endometrial thickness less than 6 mm despite conventional treatment with low dose 6 mg estradiol in 10th day cycles. They randomized and divided to groups of 50 patients and after taking testimonial from study will start. Excluding factors: platelet dysfunction syndrome, thrombocytopenia, continued use of the NSAIDs in the past 48 hours, use corticosteroid during the past month, smoking, history of cancer, recent fever, $plt < 105000$. In conventional treatment method Estradiol Valerate at 6 mg per day was given on day 2 of menstruation cycle and in all case to 8 mg increases and the maximum dose was 8 mg per day. Similarly in first group the medication is continued and second group candidate for PRP. On the 10th day of HRT cycle 15 cc of venous blood was drawn from the syringe pre-filled with 5 cc of anticoagulant solution (ACD-A) and centrifuged immediately at 200 gr for 10 min. The blood was divided

into three layers: red blood cells at the bottom, cellular plasma in the supernatant and a buffy coat layer between them. The plasma layer and buffy coat were collected to another tube and re-centrifuged 500 gr for 10 min. The resulting pellet of platelets was mixed with 1 cc of supernatant and then 0.5-1 cc of PRP was obtained. It was infused into the uterus cavity immediately with Tomcat catheter. Endometrial thickness was re-assessed 72 hours later. If the endometrial thickness was satisfied infusion of PRP was performed in 72 hr after first infusion. At last 2 groups of case and control will be compared with each other by endometrial thickness before and after PRP infusion, implantation rate, pregnancy rate and number of canceling cycles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102510210N6**

Registration date: **2016-10-30, 1395/08/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Afsun Zarei

Name of organization / entity

Shiraz University of Medical Sciences

Country

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zareia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz university of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of intrauterine infusion of autologous platelet-rich plasma (PRP) on endometrial thickness and pregnancy rate as secondary endpoint in FET cycles.

Public title

effect of platelet-rich plasma (PRP) on fertility in women with thin endometrium

Purpose

Treatment

Inclusion/Exclusion criteria

All patient with infertility that refer to mother and child hospital due to embryo transfer and recently despite conventional treatment with low dose of estradiol (6 mg) in 10th day cycles have endometrial thickness less than 6 mm no have above factors or no agree of patients platelet dysfunction, thrombocytopenia, continue using NSAIDs in the recent 48 hours, corticosteroids in the 1 month before, smoking, recent fever, history of cancer, Hb<, platelet<105000

Age

From 20 years old to 45 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Science Researching, Shiraz University of Medical Science

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Postal code

Approval date

2016-04-10, 1395/01/22

Ethics committee reference number

IR.SUMS.REC.1395.25

Health conditions studied

1

Description of health condition studied

noninflammatory disorder of female genital tract

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description

Endometrial thickness

Timepoint

in 10th day of cycles and 72 hr after infusion of PRP

Method of measurement

Trans vaginal sonography

Secondary outcomes

1

Description

clinical pregnancy or miscarriage

Timepoint

4week after embryo transfer

Method of measurement

trans vaginal sonography

Intervention groups

1

Description

Control group: Continue estradiol since day 2 of cycle till end of study

Category

Treatment - Drugs

2

Description

- Intrauterine infusion of 0.5 cc of platelet rich plasma (PRP) that contained platelet 4-5 times more than peripheral blood with uterine catheter is performed if endometrial thickness below 6 mm on day 10 of cycle and the procedure is repeated 72 hours later if the endometrial thickness below 6mm

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mother & Child Hospital.

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University Of Medical Science

Full name of responsible person

Dr Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University Of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty