

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### Evaluation of intrauterine Platelet Rich Plasma injection on pregnancy rate in women with implantation failure In Vitro Fertilization fertilization cycle

#### Protocol summary

##### Study aim

Evaluation of intrauterine Platelet Rich Plasma injection on pregnancy rate in women with implantation failure In Vitro Fertilization fertilization cycle

##### Design

A clinical trial with two groups of control and intervention, with parallel groups, without blinding, randomized by block method

##### Settings and conduct

Block randomized clinical trial on 90 infertile women with a history of implantation failure who are candidates for fetal embryo transfer, Zahedan Infertility Clinic

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: no underlying disease, 20 <age <40 years with 2 or 3 times implantation failure; Non-inclusion criteria: uterine anomaly, specific drug use

##### Intervention groups

intervention group: All patients will receive 6 mg/d Estradiol valerate from the second day of the menstrual cycle until the endometrial thickness reaches 8 mm, 400 mg progesterone vaginal suppository BD will be initiated. Three days later, 2-3 high-quality 8-cell embryos (day 3) will be transferred. Intrauterine infusion of concentrated platelet will be performed 48 hours before embryo transfer. Estradiol valerate and progesterone suppository will be continued after embryo transfer for two weeks. In the case of any kind of pregnancy and positive B-HCG, hormone replacement therapy will be continued until 12 weeks of pregnancy. Two embryos will be transferred for patients under 35 and three embryos for patients above 35. 0.5 ml of the concentrated platelet will be infused to the interior of the uterus wall using an IUI catheter. Pregnancy will be diagnosed with a B-HCG test and transvaginal ultrasound. Control group: All the procedures in the intervention group except intrauterine injection of plasma concentrate were performed in the control group.

##### Main outcome variables

The number of pregnancies

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180425039418N9**

Registration date: **2019-11-09, 1398/08/18**

Registration timing: **retrospective**

Last update: **2019-11-09, 1398/08/18**

Update count: **0**

##### Registration date

2019-11-09, 1398/08/18

##### Registrant information

##### Name

mohammad Ghena'at Pisheh Sanani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3343 1227

##### Email address

mohammad.ghenaat71@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of intrauterine Platelet Rich Plasma injection on pregnancy rate in women with implantation failure In Vitro Fertilization fertilization cycle

**Public title**  
The effect of intrauterine injection of plasma concentrated platelet on pregnancy rate

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Not the Underlying Disease being at the Age of 20 to 40  
 2 or 3 times implantation failure history  
**Exclusion criteria:**  
 Specific drug use Low quality embryos Endometrial growth not more than 8 mm

**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: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Convenient sampling method will be used and blocked randomization (using a random number table) will be used for patient allocation to group.

**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 Zahedan University of Medical Sciences

##### Street address

Dr.Hesabi Square, Campus of Medical Scineces

##### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

9816743463

#### Approval date

2019-03-10, 1397/12/19

#### Ethics committee reference number

IR.ZAUMS.REC.1397.486

## Health conditions studied

### 1

#### Description of health condition studied

implantation failure

#### ICD-10 code

N97.9

#### ICD-10 code description

Female infertility, unspecified

## Primary outcomes

### 1

#### Description

The number of pregnancies

#### Timepoint

Chemical and clinical pregnancy are respectively defined as positive serum level of B-hCG two weeks after embryo transfer, and fetal heart beat in trans-vaginal sonography five weeks after embryo transfer.

#### Method of measurement

The structured checklist

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: All patients will receive 6 mg/d Estradiol valerate from the second day of the menstrual cycle until the endometrial thickness reaches 8 mm. When the endometrial thickness reached 8 mm, 400 mg progesterone vaginal suppository BD will be initiated. Three days later, 2-3 high quality (grade A or B) 8-cell embryos (day 3) will be transferred. In the case group, intrauterine infusion of concentrated platelet will be performed 48 hours before embryo transfer. Concentrated platelet-derived from autologous blood will be centrifuged in two steps. Estradiol valerate and progesterone suppository will be continued after embryo transfer for two weeks. In the case of any kind of pregnancy and positive B-hCG, hormone replacement therapy will be continued until 12 weeks of pregnancy. All embryos will be transferred by infertility fellowship under the sonography guide. Two embryos will be transferred for patients under 35 and three embryos for patients above 35. On the day of consecrated platelet

infusion, 17.5 ml of venous blood will be taken in a syringe containing 2.5 ml of citric acid (anti-coagulation solution) which will be immediately centrifuged at 1200 rpm for 12 minutes to separate blood cells. Then, plasma is centrifuged at 3300 rpm for 7 minutes to achieve concentrated platelet which contains 4-5 times more platelet compared with venous blood. 0.5 ml of the concentrated platelet will be infused to the interior of the uterus wall using an IUI catheter (Takvin, made in Iran). The period before infusion will be considered as the control for each case. Chemical and clinical pregnancy are respectively defined as a positive serum level of B-hCG two weeks after embryo transfer, and fetal heartbeat in transvaginal sonography five weeks after embryo transfer.

#### Category

Treatment - Other

## 2

#### Description

Control group: All patients will receive 6 mg/d Estradiol valerate from the second day of the menstrual cycle until the endometrial thickness reaches 8 mm. When the endometrial thickness reached 8 mm, 400 mg progesterone vaginal suppository BD will be initiated. Three days later, 2-3 high quality (grade A or B) 8-cell embryos (day 3) will be transferred. Estradiol valerate and progesterone suppository will be continued after embryo transfer for two weeks. In the case of any kind of pregnancy and positive B-hCG, hormone replacement therapy will be continued until 12 weeks of pregnancy. All embryos will be transferred by infertility fellowship under the sonography guide. Two embryos will be transferred for patients under 35 and three embryos for patients above 35. Chemical and clinical pregnancy are respectively defined as a positive serum level of B-hCG two weeks after embryo transfer, and fetal heartbeat in trans-vaginal sonography five weeks after embryo transfer.

#### Category

Treatment - Other

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

Mouloud Infertility Clinic- Zahedan University of Medical Sciences

##### Full name of responsible person

Marzieh Ghasemi

##### Street address

Dr.Hesabi Square, Campus of Medical Scineces

##### City

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##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3329 5715

##### Email

public@zaums.ac.ir

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for research, Zahedan University of Medical Sciences

##### Full name of responsible person

Noormohammad Bakhshani

##### Street address

Dr.Hesabi Square, Campus of Medical Scineces

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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

Vice-chancellor for research, Zahedan 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

Zahedan University of Medical Sciences

##### Full name of responsible person

Sara Ershadi

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Dr.Hesabi Square , campus of medical sciences

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sara\_e1990@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr Marzieh Ghasemi

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mohammad Ghena'at Pisheh Sanani

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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mohammad.ghenaat71@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**

No - There is not 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**

No - There is not a plan to make this available