

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### comparisson of the effectiveness of intrauterine infusion of platelet-rich plasma versus no intervention on pregnancy rates in infertile women with repeated implantation failure

#### Protocol summary

##### Study aim

Determination the effect of platelet-rich plasma on pregnancy rates in infertile women with repeated implantation failure.

##### Design

Randomized, not blind, double center, phase 2.

##### Settings and conduct

Ninety infertile women with repeated implantation failure who attending in infertility department in Imam khomainsi Hospital, Mazandaran University of Medical Sciences, Sari, Iran, divided in two groups based on random numbers table. Patients and physician became aware and informed from intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 20 to 40 years, uterine tubal patency, prior three or more failed in vitro fertilization cycles. Exclusion criteria: Body mass index over the 30 kilogram per meter square, hematologic, immunologic, hormonal, genetic and renal disorders.

##### Intervention groups

Intervention 1: Intrauterine infusion of platelet-rich plasma 48 hours before embryo transfer. Intervention 2: Freeze embryo transfer.

##### Main outcome variables

Clinical pregnancy rate

#### General information

##### Reason for update

##### Acronym

PRP

##### IRCT registration information

IRCT registration number: **IRCT20160815029374N2**

Registration date: **2018-01-16, 1396/10/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-16, 1396/10/26**

Update count: **0**

##### Registration date

2018-01-16, 1396/10/26

##### Registrant information

###### Name

Marzieh Zamaniyan

###### Name of organization / entity

Mazandaran University of Medical Sciences, Sari, Iran.

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3336 5724

###### Email address

m.zamaniaan@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-05-21, 1397/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparisson of the effectiveness of intrauterine infusion of platelet-rich plasma versus no intervention on pregnancy rates in infertile women with repeated implantation failure

##### Public title

Effect of PRP on pregnancy

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Women aged 20-40 year Body mass index lower than 30 Kilogram per square meter Normal husterosalpingography At least prior three failed in vitro fertilization failure

**Exclusion criteria:**  
Hematologic disorders (blood cancer, thrombocytopenia) Immunologic disorders (anti-phospholipid syndrome, thrombophilia) Hormonal disorders (diabetes, thyroid, hyperprolactinemia) Chromosomal anomalies and genetics (hereditary or congenital) Renal failure

**Age**  
From **20 years** old to **40 years** old

**Gender**  
Female

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **90**

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

**Randomization description**  
Randomization is done based on the random number table on the day of progesterone initiation in freeze embryo transfer cycle by one nurse. In fact, only the nurse knows which patient is under the PRP infusion, or not. Physicians do not know which patient is undergoing PRP, but patients know about the intervention due to informed consent, therefore, it is not possible to concealed the patients in this 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 Mazandaran University of Medical Sciences

**Street address**

No. 5, third floor, Cancer ward, Imam Khomeini Hospital, Amir Mazandarani Ave, Diabetes Research Center.

**City**

Sari

**Province**

Mazandaran

**Postal code**

3313148166

**Approval date**

2017-05-27, 1396/03/06

**Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.96.2911

## Health conditions studied

### 1

**Description of health condition studied**

Diseases of the genitourinary system

**ICD-10 code**

N97; N98

**ICD-10 code description**

Female infertility; Complications associated with artificial fertilization

## Primary outcomes

### 1

**Description**

Clinical pregnancy rate

**Timepoint**

Forth weeks after embryo transfer

**Method of measurement**

Questionnaire

## Secondary outcomes

### 1

**Description**

Miscarriage rates

**Timepoint**

Till twenty weeks after embryo transfer

**Method of measurement**

Questionnaire

### 2

**Description**

Implantation rate

**Timepoint**

Forth weeks after embryo transfer

**Method of measurement**

Questionnaire

## Intervention groups

### 1

**Description**

Intervention group: Intrauterine infusion of 0.5 CC of autologus platelet-rich plasma (has 4-6 times platelet concentration rather than peripheral blood by IUI catheter(Takvin company, Iran) 48 hours before freeze embryo transfer.

**Category**

Treatment - Other

**2****Description**

Control group: Transfer of three Freeze embryos by chateter ( Cook, USA) under ultrasonographic guidance.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomaini Hospital

**Full name of responsible person**

Marzieh Zamaniyan

**Street address**

No. 1, Ground floor, Infertility ward, Imam Khomeini Hospital, Amir Mazandarani Ave,

**City**

Sari

**Province**

Mazandaran

**Postal code**

3313148166

**Phone**

+98 13 3366 1700

**Email**

marziehzamaniyan@gmail.com

**Web page address****2****Recruitment center****Name of recruitment center**

Mother Clinic

**Full name of responsible person**

Sepideh Peyvandi

**Street address**

NO. 4. Second floor, White tower, Infront of the 15 Khordad, Farhang Ave

**City**

Sari

**Province**

Mazandaran

**Postal code**

1763644456

**Phone**

+98 11 4443 0507

**Email**

dr\_peyvandi@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor of Mazandaran University of Medical Science.

**Full name of responsible person**

Bahar Farshidfar

**Street address**

NO.2, Third floor, Department of Research and Technology, Teachers' Square

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3304 4001

**Fax****Email**

Blackart\_Blackart@yahoo.com

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor of Mazandaran University of Medical Science.

**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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Marzieh Zamaniyan

**Position**

Assistant professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Reproductive Health

**Street address**

No. 1, First floor, Infertility ward, Imam Khomeini Hospital, Amir Mazandarani Ave,

**City**

Sari

**Province**

Mazandaran

**Postal code**

331314816

**Phone**

+98 11333661700

**Email**

marziehzamaniyan@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Marzieh Zamaniyan

**Position**

Assistant professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Reproductive Health

**Street address**

No. 1, First floor, Infertility ward, Imam Khomeini Hospital, Amir Mazandarani Ave,

**City**

Sari

**Province**

Mazandaran

**Postal code**

3313148166

**Phone**

+98 11333661700

**Email**

marziehzamaniyan@gmail.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Marzieh Zamaniyan

**Position**

Assistant professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Reproductive Health

**Street address**

No. 1, First floor, Infertility ward, Imam Khomeini Hospital, Amir Mazandarani Ave

**City**

Sari

**Province**

Mazandaran

**Postal code**

3313148166

**Phone**

+98 11333661700

**Email**

marziehzamaniyan@gmail.com

**Web page address**

**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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable