Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

comparisson of the effectivness 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 khomaini 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.
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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 effectivness 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 (herditary 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

Questionnare

Secondary outcomes

1

Description

Miscarriage rates

Timepoint

Till twenty weeks after embryo transfer

Method of measurement

Questionnare

2

Description

Implantation rate

Timepoint

Forth weeks after embryo transfer

Method of measurement

Questionare

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,
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2

Recruitment center
Name of recruitment center
Mother Clinic
Full name of responsible person
Sepideh Peyvandi
Street address
N0. 4. Second floor, White tower, Infront of the 15 Khordad, Farhang Ave
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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
N0.2, Third floor, Department of Research and Technology, Teachers' Square
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4815733971
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Fax
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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
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Full name of responsible person

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Position

Assistant professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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