

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of autologous platelet-rich plasma on improving pregnancy outcomes in repeated implantation failure: A randomized controlled trial

Protocol summary

Study aim

determining the effect of platelet rich plasma on the improvement of pregnancy outcomes in repeated implantation failure

Design

A randomized; double-blind; controlled trial, with 118 cases in two intervention or control groups, parallel-group, phase 3, randomization with use of sealed envelopes.

Settings and conduct

Tabriz jihad daneshgahi ART center, Endometrial thickness is measured by trans vaginal ultrasound. In the intervention group, intrauterine injections of PRP are performed. PRP is prepared from autologous blood by centrifugation, and 0.5 to 1 ml of PRP is injected into the uterine cavity. After 48 hours of PRP injection, the embryos are transferred to the uterine cavity in the blastocyst stage. In the control group, the standard treatment will done to transfer the embryo to the uterine cavity without intrauterine infusion of PRP.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women 18-45 years old; with a history of RIF during ART treatments. Exclusion criteria: pregnancy, diagnosed cancers, hemoglobin less than 11 gr per decilitre, platelets less than 150,000 per cc, use of anticoagulants, use of NSAID up to 10 days before the procedure, any physical or mental illness that affects the participant's immunity and admission.

Intervention groups

Intervention group: Intrauterine injection of autologous platelet rich plasma; control group: standardized fertility treatment

Main outcome variables

Blood β HCG hormone; pregnancy sac and fetus heart rate in sonography

General information

Reason for update

data correction about sample size and IRCT update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061434525N1**

Registration date: **2017-10-07, 1396/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-12, 1401/01/23**

Update count: **2**

Registration date

2017-10-07, 1396/07/15

Registrant information

Name

Elaheh Baybordi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 7924

Email address

baybordi@acecr.ac.ir

Recruitment status

Recruitment complete

Funding source

All costs are the responsibility of East Azarbaijan ACECR Organization.

Expected recruitment start date

2017-05-01, 1396/02/11

Expected recruitment end date

2018-02-01, 1396/11/12

Actual recruitment start date

2017-05-01, 1396/02/11

Actual recruitment end date

2018-02-01, 1396/11/12

Trial completion date

2019-12-31, 1398/10/10

Scientific title

Effect of autologous platelet-rich plasma on improving pregnancy outcomes in repeated implantation failure: A randomized controlled trial

Public title

Effect of autologous platelet-rich plasma on improving pregnancy outcomes in repeated implantation failure :A randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women of childbearing age (18-45 yrs) A history of RIF (repeated implantation failure) during ART(Assisted reproductive technology) treatments

Exclusion criteria:

pregnancy, Diagnosed cancers, Hemoglobin less than 11 gr per deciliter, Patelets less than 150,000/ cc, Use of anticoagulants, Use of Non-steroidal anti-inflammatory drugs up to 10 days before the procedure, Any physical or mental illness that affects the patient's immunity and admission and disrupts the process of project implementation and patient follow-up.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **118**

Actual sample size reached: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

The method is simple randomization and using the tool of sealed envelopes. Participants select one of the envelopes and deliver it to the relevant observer. The letters A and B are written inside the envelope and the participants are divided into two groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients are unaware of the assignment to the groups. The examining physician and sonographer are unaware of the assignment of the patient to the groups. The analyzer is only aware of groups A and B and is not aware of the control and intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research Institute of Royan , ACECR

Street address

Hafez Alley,North Bani Hashem ST,Resalat High Way

City

Tehran

Province

Tehran

Postal code

148- 16635

Approval date

2017-08-15, 1396/05/24

Ethics committee reference number

IR.ACECR.ROYAN.REC.1396.183

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N98.3

ICD-10 code description

Complications of attempted introduction of embryo in embryo transfer

Primary outcomes

1

Description

Positive pregnancy report with β HCG laboratory confirmed

Timepoint

4 weeks after intervention

Method of measurement

Measurement of β HCG hormone (mg / dl) by the Laboratory

2

Description

check the pregnancy sac ,

Timepoint

3 weeks after the check of positive HCG

Method of measurement

sonography

3

Description

check the fetus heart rate

Timepoint

7 weeks after intervention

Method of measurement

sonography

Secondary outcomes

1

Description

ongoing Intrauterine pregnancy diagnosis

Timepoint

During pregnancy

Method of measurement

sonography

2

Description

ectopic pregnancy

Timepoint

During pregnancy

Method of measurement

sonography

3

Description

abortion

Timepoint

During pregnancy

Method of measurement

sonography

4

Description

live birth

Timepoint

end of pregnancy

Method of measurement

child birth

Intervention groups

1

Description

intervention group: Injection of autologous platelet-rich plasma into the uterine cavity before embryos are transferred into the uterine cavity

Category

Treatment - Other

2

Description

Control group: the standard procedure and without autologous platelet-rich plasma injection, the embryos are transferred into the uterine cavity

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

East Azarbaijan ACECR infertility treatment center

Full name of responsible person

Dr Elaheh Baybordi

Street address

East Azarbaijan ACECR infertility treatment center,
Jaam e Jam AVE

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Tabriz

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baybordi@acecr.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Dr. Jafar Mohseni

Street address

ACECR Research center, Do Kamal Ave.

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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

Iranian academic center for education culture and research

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

ACECR

Full name of responsible person

Dr Jafarzadeh

Position

ACECR Infertility treatment center management

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

ACECR

Full name of responsible person

Dr Elaheh Baybordi

Position

assistant professor of community medicine

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Specialist

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baybordi@acecr.ac.ir

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

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

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

Data Dictionary

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

Title and more details about the data/document

he completed questionnaire can be used

When the data will become available and for how long

3 months after publication

To whom data/document is available

infertility researchers

Under which criteria data/document could be used

research

From where data/document is obtainable

Elaheh Baybordi, baybordi@acecr.ac.ir

What processes are involved for a request to access data/document

after receiving the email

Comments