Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 to1 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 βHCG 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 βHCG laboratory confirmed
Timepoint
4 weeks after intervention
Method of measurement
Measurement of βHCG 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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East Azarbaijan
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Email
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 managment

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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Person responsible for scientific inquiries

Contact

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Position

assistant professor of community medicine

Latest degree

Specialist

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Public Health/Community Medicine

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Latest degree

Specialist

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

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