Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of platelet-rich plasma on clinical pregnancy outcome of women with recurrent implantation failure undergoing ART

Protocol summary

Study aim
Effects of platelet-rich plasma on implantation and pregnancy in repeated implantation failure

Design
In this clinical trial study, 45 patients with a history of recurrence of fetal implantation failures were assigned to control and intervention groups.

Settings and conduct
In this clinical trial study, all patients with a history of repeated failure of fetal implantation in previous ART cycles In the infertility center of Fatemeh Zahra, Babol, the candidate for the remobilization of the embryo has been frozen, they are entering the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy women between 18 and 40 years old BMI below 30 kg / m 2 Have at least 3 or more unsuccessful fetal transmissions Fetal removal candidate Exclusion criteria: Hemoglobin disorders (hemoglobin less than 11 mg / ml and platelet below 150,000) Immunological disorders Hormonal disorders of genetic and chromosomal anomalies Acute infection Uterus anomalies including the unicorn uterus (whether or not surgical) arcuate History of uterine enzymes such as myomectomy and cesarean section NSAID use within 10 days before intervention Corticosteroid use over the past 1 month Smoking Fever History of malignancy Coagulation disorder

Intervention groups
Control group: Estradiol is continued from the second day of the cycle to the end of the study Intervention group: Infusion of 0.5 cc of platelet rich plasma(PRP)that contained platelet 4-5 times more than peripheral blood with uterine catheter is performed if endometrial thickness below 6 mm on day 10 of cycle and the procedure is repeated 72 hours later if the endometrial thickness below 6mm.

Main outcome variables
Clinical Pregnancy, Ongoing pregnancy, Endometrial thickness, Implantation rate, Abortion rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180417039338N2**
Registration date: **2018-06-18, 1397/03/28**
Registration timing: **retrospective**

Last update: **2018-06-18, 1397/03/28**
Update count: **0**

Registration date
2018-06-18, 1397/03/28

Registrant information

Name
Zahra Basirat

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3223 8284

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z.basirat@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2018-03-21, 1397/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of platelet-rich plasma on clinical pregnancy outcome of women with recurrent implantation failure undergoing ART

Public title
effect of platelet-rich plasma(PRP)on fertility in women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy women between 18 and 40 years old BMI below 30 kg / m 2 Have at least 3 or more unsuccessful fetal transmissions Fetal removal candidate
Exclusion criteria:
Hemoglobin disorders (hemoglobin less than 11 mg / ml and platelet below 150,000) Immunological disorders Hormonal disorders of genetic and chromosomal anomalies Acute infection Uterus anomalies including the unicorn uterus (whether or not surgical) arcuate History of uterine enzymes such as myomectomy and cesarean section NSAID use within 10 days before intervention Corticosteroid use over the past 1 month Smoking Fever History of malignancy Coagulation disorder
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method was based on a random number table. By this method, the populations studied were numbered from 1 to N, then a table row and column are randomly selected. The point of intersection of the selected row and column is the start of sampling point. From this point, a cross is drawn. All numbers that appear on this cross will be selected as a sample.
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 Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran
City
Babol
Province
Mazandaran
Postal code
.
Approval date
2017-12-22, 1396/10/01
Ethics committee reference number
MUBABOL.HRI.REC.1396.222

Health conditions studied

1

Description of health condition studied
Noninflammatory disorder of female genital tract
ICD-10 code
N98.9
ICD-10 code description
Complication associated with artificial fertilization ,unspecified

Primary outcomes

1

Description
Fetal Vision Imaging
Timepoint
Week 5 after ET
Method of measurement
Vaginal ultrasound

2

Description
Fetal heartburn
Timepoint
Week 5 after ET
Method of measurement
Vaginal ultrasound

3

Description
Endometrial thickness
Timepoint
in 10th day of cycles and 72 hr after infusion of PRP
Method of measurement
Trans vaginal sonography

Secondary outcomes

1

Description
Determine the amount of implantation
Timepoint
4week after embryo transfer
Method of measurement
Trans vaginal sonography

2

Description
Clinical pregnancy or miscarriage
Timepoint
4week after embryo transfer
Method of measurement
Trans vaginal sonography

Intervention groups

1

Description
Control group: Continue estradiol since day 2 of cycle till end of study
Category
Treatment - Drugs

2

Description
Intervention group: Infusion of 0.5 cc of platelet rich plasma(PRP)that contained platelet 4-5 times more than peripheral blood with uterine catheter is performed if endometrial thickness below 6 mm on day 10 of cycle and the procedure is repeated 72 hours later if the endometrial thickness below 6mm.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Center of Fatima Zahra Babol
Full name of responsible person
Dr. Sedigheh Esmaelzadeh
Street address
Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr. Reza Ghadimi
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Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Aghajanzadeh
Position
Resident of Obstetrics and Gynecology
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available