

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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 / m² 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)

Phone

+98 11 3223 8284

Email address

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 / m² 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

City

Babol

Province

Mazandaran

Postal code

.

Phone

+98 11 3223 8284

Fax

+98 11 3223 8284

Email

sesmael@yahoo.com

Web page address

<http://www.mubabol.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

.

Phone

+98 11 3219 7667

Email

rezaghadimi@yahoo.com

Web page address

<http://www.mubabol.ac.ir/>

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

Obstetrics and Gynecology

Street address

Babol University of Medical Sciences, Ganjafrooz

Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

.

Phone

+98 11 3223 8284

Email

aghanjanzadeh@yahoo.com

Web page address

<http://www.mubabol.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Sedigheh Esmailzadeh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

.

Phone

+98 11 3223 8284

Email

sesmael@yahoo.com

Web page address

<http://www.mubabol.ac.ir/>

Person responsible for updating data

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

Gynecology and Obstetrics

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

.

Phone

+98 11 3223 8284

Email

Aghajanzadeh@yahoo.com

Web page address

<http://www.mubabol.ac.ir/>

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