

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of intrauterine Platelet Rich Plasma injection on pregnancy rate in women with implantation failure In Vitro Fertilization fertilization cycle

Protocol summary

Study aim

Evaluation of intrauterine Platelet Rich Plasma injection on pregnancy rate in women with implantation failure In Vitro Fertilization fertilization cycle

Design

A clinical trial with two groups of control and intervention, with parallel groups, without blinding, randomized by block method

Settings and conduct

Block randomized clinical trial on 90 infertile women with a history of implantation failure who are candidates for fetal embryo transfer, Zahedan Infertility Clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria: no underlying disease, 20 <age <40 years with 2 or 3 times implantation failure; Non-inclusion criteria: uterine anomaly, specific drug use

Intervention groups

intervention group: All patients will receive 6 mg/d Estradiol valerate from the second day of the menstrual cycle until the endometrial thickness reaches 8 mm, 400 mg progesterone vaginal suppository BD will be initiated. Three days later, 2-3 high-quality 8-cell embryos (day 3) will be transferred. Intrauterine infusion of concentrated platelet will be performed 48 hours before embryo transfer. Estradiol valerate and progesterone suppository will be continued after embryo transfer for two weeks. In the case of any kind of pregnancy and positive B-HCG, hormone replacement therapy will be continued until 12 weeks of pregnancy. Two embryos will be transferred for patients under 35 and three embryos for patients above 35. 0.5 ml of the concentrated platelet will be infused to the interior of the uterus wall using an IUI catheter. Pregnancy will be diagnosed with a B-HCG test and transvaginal ultrasound. Control group: All the procedures in the intervention group except intrauterine injection of plasma concentrate were performed in the control group.

Main outcome variables

The number of pregnancies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180425039418N9**

Registration date: **2019-11-09, 1398/08/18**

Registration timing: **retrospective**

Last update: **2019-11-09, 1398/08/18**

Update count: **0**

Registration date

2019-11-09, 1398/08/18

Registrant information

Name

mohammad Ghena'at Pisheh Sanani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3343 1227

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of intrauterine Platelet Rich Plasma injection on pregnancy rate in women with implantation failure In Vitro Fertilization fertilization cycle

Public title
The effect of intrauterine injection of plasma concentrated platelet on pregnancy rate

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Not the Underlying Disease being at the Age of 20 to 40
 2 or 3 times implantation failure history
Exclusion criteria:
 Specific drug use Low quality embryos Endometrial growth not more than 8 mm

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Convenient sampling method will be used and blocked randomization (using a random number table) will be used for patient allocation to 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 Zahedan University of Medical Sciences

Street address

Dr.Hesabi Square, Campus of Medical Scineces

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.ZAUMS.REC.1397.486

Health conditions studied

1

Description of health condition studied

implantation failure

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

The number of pregnancies

Timepoint

Chemical and clinical pregnancy are respectively defined as positive serum level of B-hCG two weeks after embryo transfer, and fetal heart beat in trans-vaginal sonography five weeks after embryo transfer.

Method of measurement

The structured checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients will receive 6 mg/d Estradiol valerate from the second day of the menstrual cycle until the endometrial thickness reaches 8 mm. When the endometrial thickness reached 8 mm, 400 mg progesterone vaginal suppository BD will be initiated. Three days later, 2-3 high quality (grade A or B) 8-cell embryos (day 3) will be transferred. In the case group, intrauterine infusion of concentrated platelet will be performed 48 hours before embryo transfer. Concentrated platelet-derived from autologous blood will be centrifuged in two steps. Estradiol valerate and progesterone suppository will be continued after embryo transfer for two weeks. In the case of any kind of pregnancy and positive B-hCG, hormone replacement therapy will be continued until 12 weeks of pregnancy. All embryos will be transferred by infertility fellowship under the sonography guide. Two embryos will be transferred for patients under 35 and three embryos for patients above 35. On the day of consecrated platelet

infusion, 17.5 ml of venous blood will be taken in a syringe containing 2.5 ml of citric acid (anti-coagulation solution) which will be immediately centrifuged at 1200 rpm for 12 minutes to separate blood cells. Then, plasma is centrifuged at 3300 rpm for 7 minutes to achieve concentrated platelet which contains 4-5 times more platelet compared with venous blood. 0.5 ml of the concentrated platelet will be infused to the interior of the uterus wall using an IUI catheter (Takvin, made in Iran). The period before infusion will be considered as the control for each case. Chemical and clinical pregnancy are respectively defined as a positive serum level of B-hCG two weeks after embryo transfer, and fetal heartbeat in transvaginal sonography five weeks after embryo transfer.

Category

Treatment - Other

2

Description

Control group: All patients will receive 6 mg/d Estradiol valerate from the second day of the menstrual cycle until the endometrial thickness reaches 8 mm. When the endometrial thickness reached 8 mm, 400 mg progesterone vaginal suppository BD will be initiated. Three days later, 2-3 high quality (grade A or B) 8-cell embryos (day 3) will be transferred. Estradiol valerate and progesterone suppository will be continued after embryo transfer for two weeks. In the case of any kind of pregnancy and positive B-hCG, hormone replacement therapy will be continued until 12 weeks of pregnancy. All embryos will be transferred by infertility fellowship under the sonography guide. Two embryos will be transferred for patients under 35 and three embryos for patients above 35. Chemical and clinical pregnancy are respectively defined as a positive serum level of B-hCG two weeks after embryo transfer, and fetal heartbeat in trans-vaginal sonography five weeks after embryo transfer.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mouloud Infertility Clinic- Zahedan University of Medical Sciences

Full name of responsible person

Marzieh Ghasemi

Street address

Dr.Hesabi Square, Campus of Medical Scineces

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Noormohammad Bakhshani

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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

Vice-chancellor for research, Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Sara Ershadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Marzieh Ghasemi

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Ghena'at Pisheh Sanani

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available