

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of clinical pregnancy outcome between intrauterine injection of platelet rich plasma (PRP) and granulocyte colony stimulating factor (G-CSF) in patients with more than two failed embryo transfer cycles - clinical trial

Protocol summary

Study aim

The aim of the present study is the comparison of the clinical pregnancy outcomes of intrauterine injection of platelet-enriched plasma (PRP) and granulocyte colony-stimulating factor (G-CSF) in patients with more than two failed embryo transfer cycles.

Design

An uncontrolled, not blind, randomized clinical trial with a parallel-group design of 198 patients, enrolled between 2021 and 2022.

Settings and conduct

The present unblinded study will be performed at Mehr Medical Institute. Two days before embryo transfer, 1.5 ml of lympho-PRP will be prepared with a platelet concentration of 4 to 5 times of basal blood, with 2000 lymphocytes / ml. Intrauterine injection of 1 ml of lympho-PRP will be performed using an IUI catheter. Intrauterine G-CSF: On the day of progesterone administration, 1 ml of G-CSF (gu300) will be injected into the endometrial cavity using an IUI catheter.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with more than two failed embryo transfer cycles with top and good embryos; Age <41 years old. Exclusion criteria: contraindications for G-CSF use; contraindications for PRP use; Poor ovarian response according to Bologna criteria; PGS / PGD cycles; Genetic disorders; Ovum donor and surrogacy; Severe endometriosis; Severe male factor; Cycles without transferable embryos; G-CSF allergy.

Intervention groups

Intrauterine PRP: Two days before embryo transfer, intrauterine injection of 1 ml of lympho-PRP will be performed using an IUI catheter. Intrauterine G-CSF: On the day of progesterone administration, 1 ml of G-CSF (gu300) will be injected into the endometrial cavity using an IUI catheter.

Main outcome variables

Clinical pregnancy; Ongoing pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180528039878N3**

Registration date: **2021-05-08, 1400/02/18**

Registration timing: **prospective**

Last update: **2021-05-08, 1400/02/18**

Update count: **0**

Registration date

2021-05-08, 1400/02/18

Registrant information

Name

Marzieh Mehrafza

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of clinical pregnancy outcome between intrauterine injection of platelet rich plasma (PRP) and granulocyte colony stimulating factor (G-CSF) in patients with more than two failed embryo transfer cycles -clinical trial

Public title
Comparison of intrauterine PRP versus G-CSF in RIF patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

More than two failed cycles of top and good embryo transfer Age <41 years

Exclusion criteria:

G-CSF Contraindications, PRP Contraindications, Poor ovarian response according to Bologna criteria, PGS / PGD cycles, Genetic disorders, Ovum donor or surrogacy, Severe endometriosis, Severe male factor, No embryo transfer cycles G-CSF allergy

Age
To **41 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **198**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be done using seal enveloped software. The list of blocks will be written and numbers will be assigned to them (AABB (1) - ABAB (2) -ABBA (3) - BBAA (4) - BABA (5) - BAAB (6)), then random numbers between one and six (For example, 1 4 5, etc.) will be select and finally the treatment allocation list based on previous random numbers (AABB, BBAA, BABA, etc.) will be specified.

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

Guilan University of Medical Sciences

Street address

Shahid Siadati Ave - Namjoo St - Rasht- IRAN

City

Rasht

Province

Guilan

Postal code

66949-41446

Approval date

2021-04-07, 1400/01/18

Ethics committee reference number

IR.GUMS.REC.1400.017

Health conditions studied

1

Description of health condition studied

Repeated implantation failure

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

Six weeks after embryo transfer

Method of measurement

Ultrasonography

2

Description

Ongoing pregnancy

Timepoint

Twelve weeks after embryo transfer

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

Biochemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

beta-hCG measurement

Intervention groups

1

Description

Intervention group: Intrauterine injection of PRP: Endometrial preparation will be started using estradiol (4 mg daily) and ASA. From day 6, 6 mg of estradiol will be given daily. Depending on the age of the embryo, progesterone (400 mg suppository, 100 mg intramuscular) will be given for 3 to 5 days. Two days before embryo transfer, peripheral venous blood (8.5 ml) will be drawn into a 10 ml syringe containing 1.5 ml of anticoagulant solution. According to ROOYAGEN's recommended instructions, 1.5 ml of lympho-PRP with a platelet concentration of 4 to 5 times the basal blood with 2000 lymphocytes / ml will be prepared. Intrauterine injection of 1 ml of lympho-PRP will be performed using an IUI catheter.

Category

Treatment - Other

2

Description

Intervention group: Intrauterine G-CSF: Endometrial preparation will be started using estradiol (4 mg daily) and ASA. From day 6, 6 mg of estradiol will be given daily. Depending on the age of the embryo, progesterone (400 mg suppository, 100 mg intramuscular) will be given for 3 to 5 days. On the day of progesterone initiation, 1 ml G-CSF (gu300) will be injected into the endometrial cavity using an IUI catheter.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr Medical Institute

Full name of responsible person

Marzieh Mehrafza

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Mehr Medical Institute, Ershad St, Ansari Blv, Rasht, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Mehr Medical Institute

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Mehr Medical Institute

Full name of responsible person

Marzieh Mehrafza

Position

Fertility Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Reproductive Biology

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Person responsible for scientific inquiries

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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

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