Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the application platelet rich plasma in the treatment of patients with recurrent implantation failure in IVF-ICSI & freeze embryo transfer cycles

Protocol summary

Study aim

Comparison of live births rate in embryo transfer cycles with and without intra uterine infusion of platelet rich plasma (PRP) in patients with recurrent implantation failure.

Design

A randomized clinical trial with control group, open label, two arm parallel group design of 40 patients. Randomization is performed using a computer-generated random assignment schedule for each patient. Sealed and numbered envelopes are used to conceal the treatment allocation until randomization.

Settings and conduct

Female infertility Clinic of ROYAN institute.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Infertile women with a history of recurrent implantation failure; Age 20-40 years; Body Mass Index 19-29 Kg/m2; Having at least three good quality embryo. Exclusion criteria: Women with hematologic and autoimmune disorders; Couples with chromosomal and genetic abnormalities; Women with uterine anomalies; Women with uterine and ovaries surgical history; Women with endometriosis and adenomyosis; Women with hydrosalpinx; Women with uterine fibroids; Women with recurrent abortion history; Cervicitis; History of fever condition; Use of corticosteroids or non-steroid anti-inflammatories; Anemia, thrombocytopenia, platelet dysfunction syndrome, hypofibrinogenemia; Septicemia, active infections with Pseudomonas, Klebsiella or Enterococcus; History of cancer.

Intervention groups

1. The group of embryo transfer with intrauterine infusion of PRP. One milliliter of PRP will be injected into the patients' uterine cavity using an embryo transfer catheter, 48 hours before embryo transfer. 2. The group of embryo transfer without intrauterine infusion of PRP. In order to eliminate the effects of catheter insertion, the same catheter will be applied to the patients' uterine cavity without any injections, 48 hours before the embryo transfer.

Main outcome variables

Live births rate

General information

Reason for update

Acronym

PRP-RIF

IRCT registration information

IRCT registration number: **IRCT20080831001141N37**
Registration date: **2021-01-06, 1399/10/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-06, 1399/10/17**
Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

Kiandokht Kiani

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the application platelet rich plasma in the treatment of patients with recurrent implantation failure in IVF-ICSI & freeze embryo transfer cycles

Public title

Platelet rich plasma and recurrent implantation failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women with a history of recurrent implantation failure Age 20-40 years Body Mass Index 19-29 Kg/m2 Having at least three good quality embryos

Exclusion criteria:

Women with hematologic and autoimmune disorders Couples with chromosomal and genetic abnormalities Women with uterine anomalies Women with uterine and ovaries surgical history Women with endometriosis and adenomyosis Women with hydrosalpinx Women with uterine fibroids Women with recurrent abortion history Cervicitis History of fever condition (in up to 2 weeks before the intervention) Use of corticosteroids (in up to 2 weeks before the intervention) or non-steroid anti-inflammatories (in up to 48 hours before the intervention) Anemia, thrombocytopenia, platelet dysfunction syndrome, hypofibrinogenemia Septicemia, active infections with Pseudomonas, Klebsiella or Enterococcus History of cancer

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: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method is designed by epidemiologist using STATA software version 13 and the number of blocks considered is 8. The random allocation list for patients is solely available to the epidemiologist. In order to hide the random allocation process, a total of 40 envelopes are prepared, and only the methodologist has been aware of table of random numbers. When the doctor declared the patient's eligibility, the methodologist provided the doctor with the envelope. The group will be selected and based on the type of group mentioned in the envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

مرکز ثبت کارآزمایی های بالینی ایالات متحده آمریکا (WWW.clinicaltrial.gov)

Secondary trial Id

NCT03996837

Registration date

2019-06-25, 1398/04/04

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Royan Institute

Street address

Royan Institute, Number 12, East Hafez Avenue, Banihashem Street, Resalat Highway.

City

Tehran

Province

Tehran

Postal code

148- 16635

Approval date

2017-08-15, 1396/05/24

Ethics committee reference number

IR.ACECR.ROYAN.REC.1396.99

Health conditions studied

1

Description of health condition studied

recurrent implantation failure

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Live birth rate; live birth is defined in which a live fetus is delivered beyond 20 completed weeks of gestational.

Timepoint
Only once; at least 20 weeks after embryo transfer.
Method of measurement
Clinical information.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group of embryo transfer (fresh and or freeze) with intra uterine infusion of platelet rich plasma (PRP). In in vitro fertilization cycles, ovarian stimulation will be performed through the standard protocol using gonadotropin-releasing hormone (GnRH) agonist. In freeze embryo transfer cycles, the endometrial preparation will be performed through the standard protocol using GnRH agonist. One milliliter of PRP will be injected into the patients' uterine cavity using an embryo transfer catheter, 48 hours before embryo transfer.
Category
Treatment - Other

2

Description
Control group: The group of embryo transfer (fresh and or freeze) without intra uterine infusion of PRP. In in vitro fertilization cycles, ovarian stimulation will be performed through the standard protocol using GnRH agonist. In freeze embryo transfer cycles, the endometrial preparation will be performed through the standard protocol using GnRH agonist. In order to eliminate the effects of catheter insertion, the same catheter will be applied to the patients' uterine cavity without any injections, 48 hours before the embryo transfer.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Center of ROYAN
Full name of responsible person
Mehri Mashayekhy
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
ROOYAGEN company
Proportion provided by this source
10
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
ROYAN Institute
Full name of responsible person
Mehri Mashayekhy
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Clinical study report (published article)

When the data will become available and for how long
After the publication of the article

To whom data/document is available
Available to the public.

Under which criteria data/document could be used
Scientific use by citing the source.

From where data/document is obtainable
Dr. Mehri Mashayekhy Email: dr.mashayekhy@yahoo.com

What processes are involved for a request to access data/document
Request via e-mail

Comments