

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison effect intrauterine administration of peripheral blood lymphocyte cells on pregnancy outcome on patients with repeated implantation failure on fresh embryo transfer cycles and frozen/thawed embryo transfer cycles

Protocol summary

Study aim

The aim of this study was to determine effect of intrauterine administration of peripheral blood lymphocyte cells on pregnancy outcome on RIF's patients.

Design

In this clinical trial study all women who have entered in the study were divided in three groups: fresh embryo transfer, frozen/thawed embryo transfer and control group.

Settings and conduct

In all three groups ovulation induction was done. After oocyte retrieval, cumulus cells were removed from oocytes then sperm was injected into denuded oocytes.

Participants/Inclusion and exclusion criteria

This clinical trial is conducted on women who have been treated in fresh and frozen/thawed infertility treatment cycles and have a history of RIF. The criteria for entering the study include: 1. Having 3≤ failure in IVF or ICSI cycle 2. No poor ovarian reserve (FSH <15 mIU / ml) 3. No history of clinical pregnancy (primary infertility). 4. Endometrial thickness 7 < mm after ovulation induction 5. BMI <30 Exclusion criteria included: 1. History of repeated infectious diseases in the past 2. Endometriosis 3. Uterine pathologies including uterine myoma 4. Etiologies known as repeated implantation failure including chromosomal abnormalities

Intervention groups

1. A group of patients undergoing lymphocyte therapy in the fresh embryo transfer cycle. in these patients, 5 cc blood samples were taken in one day before day of HCG injection, and then their peripheral blood lymphocytes were isolated on the same day and 48-72hours were placed in the culture medium. On ovulation day, A single dose of 0.4 CC lymphocytes are injected into the uterus with an IUI catheter. The embryos transferred to the

uterus on the second to third day with the embryo transfer catheter. 2-Another group of patients are in the freeze embryo transfer lymphocyte therapy cycle. Five days before embryo transfer, 5 cc blood samples were taken and their peripheral blood lymphocytes were immediately isolated on the same day, and 48-72 hours were placed in the medium. Then, a single dose of 0.4 CC lymphocytes are injected into the uterus with an IUI catheter. 2-3 days after the injection of the lymphocytes, the frozen embryos are thawed and transferred to the uterus with the embryo transfer catheter. 3- control group haven't any blood sampling and lymphocyte injection into the uterus. In all three groups, support for the luteal phase is performed by administering two cyclogest vaginal suppositories for up to two weeks. The blood BHCG is measured 14 days later.

Main outcome variables

Finally, the outcome of pregnancy is recorded in three groups and the pregnancy rate will be compared in three groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140707018381N2**

Registration date: **2017-12-03, 1396/09/12**

Registration timing: **retrospective**

Last update: **2017-12-03, 1396/09/12**

Update count: **0**

Registration date

2017-12-03, 1396/09/12

Registrant information

Name

Ahmad Hosseini

Name of organization / entity

Shahid Beheshti University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Behashti University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect intrauterine administration of peripheral blood lymphocyte cells on pregnancy outcome on patients with repeated implantation failure on fresh embryo transfer cycles and frozen/thawed embryo transfer cycles

Public title

Comparison effect intrauterine administration of peripheral blood lymphocyte cells on pregnancy outcome on patients with repeated implantation failur

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: at least ≥ 3 previous implantation failure in IVF or ICSI cycles No history of clinical pregnancy (primary infertility) No poor ovarian reserve (FSH < 15 mIU/ml) Endometrial thickness $7 <$ in ovulation induction time BMI < 30

Exclusion criteria:

Women with history of repeated infectious diseases in the past; Endometriosis Uterine pathology such as uterine lymphomas The known etiology of recurrent implantation failure as chromosomal disorders were excluded from the study

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

By random number table couples that participated in the study divided into experiments and control groups.

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 Shahid Beheshti University of Medical Sciences

Street address

Faculty of medicine, Arabi Ave, Daneshjo street, Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2016-07-17, 1395/04/27

Ethics committee reference number

IR.SBMU.REC.1395.38

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

multiple pregnancy rate

Timepoint

14 weeks of pregnancy

Method of measurement

sonography

2

Description

abortion rate

Timepoint

20 weeks after pregnancy

Method of measurement

sonography

Secondary outcomes

1

Description

clinical pregnancy rate

Timepoint

after intervention

Method of measurement

sonography

Intervention groups

1

Description

1. A group of patients undergoing lymphocyte therapy in the fresh embryo transfer cycle. In these patients, 5 cc blood samples were taken in one day before day of HCG injection, and then their peripheral blood lymphocytes were isolated on the same day and 48-72 hours were placed in the culture medium. On ovulation day, a single dose of 0.4 CC lymphocytes are injected into the uterus with an IUI catheter. The embryos transferred to the uterus on the second to third day with the embryo transfer catheter.

Category

Treatment - Drugs

2

Description

2-Another group of patients are in the frozen/thawed embryo transfer lymphocyte therapy cycle. Five days before embryo transfer, 5 cc blood samples were taken and their peripheral blood lymphocytes were immediately isolated on the same day, and 48-72 hours were placed in the medium. Then, a single dose of 0.4 CC lymphocytes are injected into the uterus with an IUI catheter. 2-3 days after the injection of the lymphocytes, the frozen embryos are thawed and transferred to the uterus with the embryo transfer catheter.

Category

Treatment - Drugs

3

Description

3. The control group haven't any blood samplings and lymphocyte injection into the uterus

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Genetics & In Vitro Assisted Reproductive (GIVAR) center, Erfan hospital

Full name of responsible person

Dr. Fattaneh Farifteh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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

Shahid beheshti University of Medical Sciences

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All interventions in the patient's file will be recorded and archived in the Erfan hospital. All data obtained from this study will be released after being unidentified studies participants.

When the data will become available and for how long

Get started 6 months after publishing study results

To whom data/document is available

he findings of this study will be accessible to all individuals.

Under which criteria data/document could be used

To improve pregnancy outcomes in infertility clinics

From where data/document is obtainable

Dr Fattaneh Farifteh

What processes are involved for a request to access data/document

Receiving the author's confirmation and obtaining approval from the director of the Infertility Clinic of the Erfan Hospital

Comments