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 Beheshty 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
Street address
Erfan hospital, Bakhshayesh St, Sarv st., Tehran
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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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http://phasco.com/LabDirectory.aspx?lid=853
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

Full name of responsible person

Fattaneh Farifteh

Position

Academic staff

Latest degree

Ph.D.

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)

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