

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation effect intrauterine administration of peripheral blood lymphocyte cells on expression of endometrial estrogen and progesterone receptor on implantation window in women with repeated implantation failure

Protocol summary

Study aim

Determination the effect of intrauterine administration of peripheral blood lymphocyte cells on expression of endometrial estrogen and progesterone receptor on implantation window in women with repeated implantation failure

Design

In this clinical trial study all women who have entered in the study were divided in two groups: lymphocyte therapy and control group.

Settings and conduct

A group of patients is in the lymphocyte therapy cycle. Five days before endometrial biopsy, 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, 2 days before endometrial biopsy, a single dose of 0.4 CC lymphocytes is injected into the uterus with an IUI catheter. The biopsy samples will be prepared for qPCR and immunohistochemical staining. The control group haven't any blood samplings and lymphocyte injections into the uterus. The endometrial biopsy will be performed, at the implantation window time of each menstrual cycle. The biopsy samples will be prepared for qPCR and immunohistochemical staining. The estrogen and progesterone receptor expression in uterus endometrium is measured by qPCR and immunohistochemical staining technique.

Participants/Inclusion and exclusion criteria

This clinical trial is conducted on infertile women who have a history of RIF.

Intervention groups

A group of patients is in the lymphocyte therapy cycle. The control group

Main outcome variables

The mRNA and protein expression of the estrogen

receptor and progesterone in uterus endometrium

General information

Reason for update

sample size revision

Acronym

IRCT registration information

IRCT registration number: **IRCT20140707018381N3**

Registration date: **2018-07-30, 1397/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-19, 1401/12/28**

Update count: **4**

Registration date

2018-07-30, 1397/05/08

Registrant information

Name

Ahmad Hosseini

Name of organization / entity

Shahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 9153

Email address

ahmad-hosseini@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-06, 1396/10/16

Expected recruitment end date

2019-08-05, 1398/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation effect intrauterine administration of peripheral blood lymphocyte cells on expression of endometrial estrogen and progesterone receptor on implantation window in women with repeated implantation failure

Public title

Evaluation effect intrauterine administration of peripheral blood lymphocyte cells on expression of endometrial estrogen and progesterone receptor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

At least ≥ 3 previous implantation failure in IVF or ICSI cycles No history of clinical pregnancy (primary infertility) not receiving any steroidal hormone ≥ 2 months were entered in this study

Exclusion criteria:

genetic disorders history of repeated infectious diseases Endometriosis uterine anatomic abnormalities

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 22

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using computer-generated tables.

Blinding (investigator's opinion)

Single blinded

Blinding description

All qualitative and quantitative assessment of samples was done by a single, blinded investigator.

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.RETECH.REC.1395.402

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**

The mRNA levels of both estrogen receptors and progesterone receptors in endometrial tissues

Timepoint

at the implantation window time, during the mid-secretory phase (LH+7 days) of each menstrual cycle

Method of measurement

The sample of tissue is analyzed using the quantitative real-time polymerase chain reaction (qRT-PCR) technique

Secondary outcomes**1****Description**

The protein expression estrogen receptors and progesterone receptors in endometrial tissues

Timepoint

at the implantation window time, during the mid-secretory phase (LH+7 days) of each menstrual cycle

Method of measurement

immunohistochemical staining

Intervention groups

1

Description

Intervention group: A group of patients are in lymphocyte therapy group. Five days before endometrial biopsy, 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, 2 days before endometrial biopsy, a single dose of 0.4 CC lymphocytes are injected into the uterus with an IUI catheter. Endometrial biopsy will be performed, at the implantation window time, during the mid-secretory phase (LH+7 days) of each menstrual cycle. The biopsy samples will be prepared for qPCR and immunohistochemical staining.

Category

Treatment - Drugs

2

Description

Control group: The control group haven't any blood samplings and lymphocyte injections into the uterus. The endometrial biopsy will be performed, at the implantation window time, during the mid-secretory phase (LH+7 days) of each menstrual cycle. The biopsy samples will be prepared for qPCR and immunohistochemical staining.

Category

Treatment - Other

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

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2235 8435

Fax

+98 21 8867 8159

Email

f.farifteh@gmail.com

Web page address

<http://phasco.com/LabDirectory.aspx?lid=853>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Ahmad Hosseini

Street address

Shahid Beheshti University of medical science, Arabi Ave, daneshjo st, Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9956

Email

profhosseini@yahoo.com

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Fattaneh Farifteh

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Shahid Beheshti University of medical science, Arabi Ave, daneshjo st, Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9956

Email

f.farifteh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Fattaneh Farifteh

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Shahid Beheshti University of medical science, Arabi Ave, daneshjo st, Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2235 9153

Email

f.farifteh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Fattaneh Farifteh

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Shahid Beheshti University of medical science, Arabi Ave, daneshjo st, Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2235 9153

Email

f.farifteh@gmail.com

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

Not applicable

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 unidentifiable 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

The 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