

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intravenous intralipid administration on reproductive outcomes for couples with recurrent implantation failure in non-donor in vitro fertilization /intracytoplasmic injection cycles

Protocol summary

Study aim

Investigating intravenous(IV) intralipid administration in people with recurrent implantation failure(RIF) during IVF/ICSI cycles.

Design

Clinical trial with a control group, with parallel groups, single-blind, randomized, phase 3 on 70 patients. The rand function of Excel software was used for randomization.

Settings and conduct

70 infertile patients with a history of frequent unexplained implantation failure referred to the infertility department of Taleghani Hospital of Tehran who were candidates for frozen embryos were randomly divided into two interventions. control groups and the intervention group received intralipid on the first day of progesterone, positive pregnancy test, and 5 weeks after embryo transfer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: embryos in ≤ 35 years and or at least 4 Day-3 embryos ≥ 35 years old with Idiopathic RIF and: normal hormonal profile of FSH, LH, TSH, PRL, and AMH; normal uterine cavity by hysteroscopy; body mass index 20–32 kg/m²; normal oocytes and embryos(grade A;B). Exclusion criteria: Women with recurrent miscarriages; with obvious reasons for IVF failure such as fibroids or polyps as assessed by hysteroscopy, age over 40 years, women undergoing donor egg IVF, low-quality embryos, severe endometriosis; contraindications for coagulation disorders, high cholesterol, liver disease, sickle cell disease; allergic to egg, lecithin or soy products.

Intervention groups

The intervention group receiving IV intralipid in patients with a history of RIF who are candidates for frozen embryo transfer(FET) and investigating pregnancy outcomes. The control group without receiving intralipid

in patients with a history of RIF who are candidates for FET and investigation of pregnancy outcomes in them.

Main outcome variables

Implantation rate, Biochemical pregnancy rate, Clinical pregnancy rate, Ongoing pregnancy rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056198N2**

Registration date: **2023-03-16, 1401/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-16, 1401/12/25**

Update count: **0**

Registration date

2023-03-16, 1401/12/25

Registrant information

Name

Nazanin Hajizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2600

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous intralipid administration on reproductive outcomes for couples with recurrent implantation failure in non-donor in vitro fertilization /intracytoplasmic injection cycles

Public title

The effect of intralipid in recurrent implantation failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with history of recurrent implantation failure who aged less than 40 years Patients with normal hormone profile Patients with BMI 20-32

Exclusion criteria:

Women with recurrent pregnancy loss Women with aged more than 40 years Women with endometriosis Women with coagulation disorder Women with allergy to soya and egg Women with Liver, Heart and Renal disease Women with high cholestrole

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients with a history of repeated implantation failure in IVF cycles were divided into two groups receiving intralipid and a control group without receiving intralipid, who were assigned to one of the two treatment methods based on the randomization method with permutation blocks using Random Excel software.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants were unaware of the study group assignment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic commitee of Shahid Beheshti University Of Medical Science

Street address

Arabi avenue, Velenjak

City

Tehran

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Tehran

Postal code

1985717413

Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.850

Health conditions studied**1****Description of health condition studied**

Infertile patient with recurrent implantation failure

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Implantation rate :The ratio of implanted embryos to transferred embryos

Timepoint

7 weeks after embryo transfer

Method of measurement

Vaginal Sonography

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

Biochemical pregnancy rate

Timepoint

14 days after embryo transfer

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group : Patients with a history of repeated implantation failure receiving Intralipid in embryo freeze transfer cycles

Category

Treatment - Drugs

2

Description

Control group : Patients with a history of repeated implantation failure receiving Intralipid in embryo freeze transfer cycles

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Nazanin Hajizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology

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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

20

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

Nazanin Hajizadeh

Position

Assistant Infertility Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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