Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of intralipid in fertility rate in recurrent implantation failure (RIF) in frozen embryo transfer against the control group

Protocol summary

Study aim

1. Investigating the rate of chemical pregnancy in patients with recurrent implantation failure receiving Intralipid compared to the control group 2. rate of clinical pregnancy 3. rate of ongoing pregnancy 4. Rate of pregnancy over 24 weeks

Design

A controlled, parallel-group, randomized, phase 3 clinical trial on 160 patients. To randomize the rand function of Excel software

Settings and conduct

This study is conducted on the patients of the infertility department of Shariati Hospital who have had at least two failed embryo transfers and have referred to begin the frozen embryo transfer cycle. The selection of patients for the control and intervention groups is done by randomization using Excel software, and first the basic information of each patient is extracted, then the control group patients undergo endometrial preparation with the conventional method of the department and the intervention group in addition to the conventional method at the beginning of the freeze cycle, on the day transfer and if the pregnancy test is positive, three weeks after the transfer, will receive 100cc of Intralipid 20% SOMF. Then the rate of chemical, clinical and pregnancy over 16 and 24 weeks in two groups is compared

Participants/Inclusion and exclusion criteria

Patients candidates for frozen embryo transfer, who have had at least two unexplained failed frozen or fresh embryo transfers. Exclusion criteria: 1. Age more than 42 years 2. BMI more than 35 3. Severe male infertility 4. AMH less than 1.5 5. Low quality embryo 6. Thrombophilia or Anti phospholipid syndrome 7. Abnormal uterine anatomy 8. Recurrent abortions

Intervention groups

recipient of 100 cc of intralipid 20%(SOMF) in beginning of freeze cycle ,day of embryo transfer and after 3 weeks of transfer if pregnancy test is positive

Main outcome variables

chemical ,clinical ,ongoing and more than 24 weeks pregnancy

General information

Reason for update

Acronym

RIF

IRCT registration information

IRCT registration number: **IRCT20220725055555N1**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-10, 1401/06/19**
Update count: **0**

Registration date

2022-09-10, 1401/06/19

Registrant information

Name

Seyyedeh Neda Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4408 8156

Email address

s.nedakazemi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of intralipid in fertility rate in recurrent implantation failure (RIF) in frozen embryo transfer against the control group

Public title

Effectiveness of intralipid in fertility rate in recurrent implantation failure (RIF) in frozen embryo transfer cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile patients with two or more implantation failures

Exclusion criteria:

Age more than42 years BMI more than 35 Familial hyperlipidemia Severe male factor infertility AMH less than 1.5 Low quality embryo Anatomical abnormality of uterus (Mullerian anomaly, sub mucosal fibroid , polyp ,hydrosalpinx ,..) Abnormal laboratory in liver function test, thyroid function test, prolactin, Lipid profile Recurrent abortion history Thrombophilia and anti phospholipid syndrome

Age

From **20 years** old to **42 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

randomization by rand function of Allocation of patients in two groups has been done by block random allocation method. Allocation sequence using the free web system www.sealedenvelope.com to generate the sequence, the number of subjects in each block is 4 and the letters A are for intervention group and letters B are for control. Finally, 72 samples (18 blocks) in two groups A and B have been produced.Excel Software

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

کمیته اخلاق دانشگاه علوم پزشکی تهران

Street address

Jalale Al Ahmad

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Tehran

Province

Tehran

Postal code

14111713135

Approval date

2022-07-29, 1401/05/07

Ethics committee reference number

IR.TUMS.MEDICIN.REC.1401.224

Health conditions studied

1

Description of health condition studied

Recurrent implantation failure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pregnancy

Timepoint

check of pregnancy test after two weeks from embryo transfer

Method of measurement

beta -HCG t titer

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

4 weeks after embryo transfer

Method of measurement

ultrasound and check of fetal heart rate

2

Description

ongoing pregnancy

Timepoint

14 weeks after embryo transfer

Method of measurement
ultrasound

Intervention groups

1

Description
Intervention group: receive intralipid in addition of ward routine protocol
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Seyyedeh Neda Kazemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr . Akbar Fotohi
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Keshavarz Blv . Qods Ave
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1417653761
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Seyyedeh Neda Kazemi
Position
post graduated fellowship
Latest degree
Specialist
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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
Not applicable
Title and more details about the data/document
result data
When the data will become available and for how long
A Year after study
To whom data/document is available
Researchers in the academic place
Under which criteria data/document could be used
crude data
From where data/document is obtainable
Seyyede Neda Kazemi s.nedakazemi@gmail .com
What processes are involved for a request to access data/document
request by e-mail
Comments