

# 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 than 42 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

##### City

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

**Street address**

Jalale Ale Ahmad

**City**

Tehran

**Province**

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**Postal code**

1411713135

**Phone**

+98 21 8490 1000

**Fax**

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**Email**

s.nedakazemi@gmail.com

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr . Akbar Fotohi

**Street address**

Keshavarz Blv . Qods Ave

**City**

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**Province**

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**Postal code**

1417653761

**Phone**

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**Email**

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

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Seyyede 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