

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### The effect of immunotherapy with injectable intervalipide in improving pregnancy outcomes in patients with a history of recurrent implantation failure in assisted reproductive therapies

#### Protocol summary

Chemical pregnancy - clinical pregnancy - abortion

##### Study aim

Investigation of the effect of immunotherapy with injectable interlipid in improving pregnancy outcomes in patients with a history of recurrent implantation failure in assisted reproductive therapies

##### Design

Random allocation to intervention and control groups in the form of random blocking of the two-way blind type with a sample size of 40 naf

##### Settings and conduct

This study is being conducted at the Milad Infertility Center affiliated to Mashhad University of Medical Sciences and includes infertile patients with a history of recurrent implantation failure who have the conditions to study and are willing to enter the study. Patients are randomly divided into two equal groups (20 people each). In the intervention group, one injection of 2 to 4 cc of intralipid 20% in 4-9 days will be stimulated and one injection will be performed with the same dose after a positive pregnancy test, and routine measures will be performed in the control group.

##### Participants/Inclusion and exclusion criteria

Entry criteria: All patients referred to Milad Infertility Center with a history of repeated implantation fractures  
Lack of entry criteria: history of fibroids, polyps, endometriosis, hydrocephalus, fat metabolism disorders, egg and soy allergy, liver, kidney, lung disease, coagulation disorders, genetic diseases and chromosomal disorders, anatomical disorders, thrombophilia, infection

##### Intervention groups

intervention group, a dose of 2-4 mg 20% intralipid in 250 ml normal saline (Sina Pakhsh Saba Co. Tehran, Iran) was injected a day before progesterone administration and the second dose was given after a positive test of pregnancy

##### Main outcome variables

#### General information

##### Reason for update

The study start date has changed. The sample size has increased, and since we also examined live births, the duration of the study has increased

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200615047781N1**

Registration date: **2020-07-08, 1399/04/18**

Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**

Update count: **1**

##### Registration date

2020-07-08, 1399/04/18

##### Registrant information

##### Name

Azade Khazaie

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3761 5166

##### Email address

azadekhazaie@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-28, 1399/10/08

##### Expected recruitment end date

2021-03-18, 1399/12/28

##### Actual recruitment start date

2020-08-10, 1399/05/20  
**Actual recruitment end date**  
2022-09-11, 1401/06/20  
**Trial completion date**  
empty

#### Scientific title

The effect of immunotherapy with injectable intervalipide in improving pregnancy outcomes in patients with a history of recurrent implantation failure in assisted reproductive therapies

#### Public title

Investigation of the effect of interlipid in patients with a history of recurrent implantation failure

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients referred to Milad Infertility Center in Mashhad with a history of repeated implantation failure

##### Exclusion criteria:

History of fibroids endometrial polyp endometriosis Hydrosalpangs Fat metabolism disorder Allergies to eggs and soy liver disease renal disease pulmonary disease Blood coagulation disorder Genetic diseases and chromosomal disorders anatomic disorders vaginal infections hormonal disorders trombophilia

#### Age

No age limit

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

- Participant
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **40**

Actual sample size reached: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random allocation list using pass software. The type of randomization is simple, and the analyst and physician will be unaware of the intervention and control groups

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

The researcher does not know how to randomize. The patient and the results evaluator are not aware of the assigned group

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of mashhad university of medical sciences

##### Street address

Dahdee Square - Razi Sharghi St. - Milad Infertility Center

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9178631973

#### Approval date

2016-11-02, 1395/08/12

#### Ethics committee reference number

ir.mums.fm.rec.1395.366

## Health conditions studied

### 1

#### Description of health condition studied

reccurent implantation failure in assisted reproductive therapies

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

chemical pregnancy rate

#### Timepoint

Two weeks after embryo transfer

#### Method of measurement

serum bhcg level

### 2

#### Description

clinical pregnancy rate

#### Timepoint

6 weeks after embryo transfer

#### Method of measurement

sonography

### 3

#### Description

abortion rate

#### Timepoint

Pregnancy loss before 12 weeks of pregnancy

**Method of measurement**

sonography

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: intervention group, a dose of 2-4 mg 20% intralipid in 250 ml normal saline (Sina Paksh Saba Co.Tehran, Iran)was injected a day before progesterone administration and the second dose was given after a positive test of pregnancy.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center****Name of recruitment center**

milad infertility center

**Full name of responsible person**

azade khazaei

**Street address**

Dehdee Square - Razi Sharghi Street

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9178631973

**Phone**

+98 51 3853 6169

**Email**

azadekhazaie@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

dr mohsen tafaghodi

**Street address**

University Street - Mashhad University of Medical Sciences

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3538 3841

**Email**

tafaghodim@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

malihe mahmodi nia

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Deh Dey Square - Razi Sharghi St. - Milad Infertility Center

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9178631973

**Phone**

+98 51 3853 6169

**Email**

mahmoudiniam@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

malihe mahmodinia

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Postal code**

9178631973

**Phone**

+98 51 3853 6169

**Email**

mahmoudiniam@mums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

nayere khadem

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Ibn Sina St. - Imam Reza Hospital

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9178631973

**Phone**

+98 51 3852 5305

**Email**

khademn@mums.ac.ir

**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