

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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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 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