

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of interlipid infusion for patients with a history of 2 unsuccessful embryo transfers

Protocol summary

Study aim

Study of interlipid infusion efficacy in patients with a 2-time embryo transfer in the infertility center of Mazandaran University of Medical Sciences

Design

This clinical trial had a control group with parallel randomized groups with 80 patients, of which 40 were in the intervention group and 40 were in the control group.

Settings and conduct

This study is performed in the infertility center of Imam Khomeini Hospital in Sari • 80 patients are randomly placed in the control and intervention group who inject 20% solution of interlipid into the intervention group before embryo transfer and then transfer, the initial result of a positive test Pregnancy is possible, also this study is one-sided blind and the patient is considered blind

Participants/Inclusion and exclusion criteria

All mothers with a history of infertility are sampled. Patients who have been sampled have a history of 2 with embryo transfer. Mothers with dangerous chromosomal abnormalities, antiphospholipid syndrome or a positive thrombophilia test, mothers with endocrine disorders, hyperlipidemia, allergies to eggs and their products are excluded from the study. Mothers over the age of 40 were also considered our exclusion criteria.

Intervention groups

Intervention group (Intralipid receptor): Intralipid receptor 20% solution in 250 cc of sterile saline, which is administered within two hours. Once between days 4 to 9 of ovarian stimulation and again on day 7 with a positive pregnancy test. Control group of 40 people: the group that does not receive the intervention

Main outcome variables

Positive pregnancy test; wife fetal heart in week 6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140305016858N5**
Registration date: **2021-06-19, 1400/03/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

Registration date

2021-06-19, 1400/03/29

Registrant information

Name

Sepideh Peyvandi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-07-11, 1400/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of interlipid infusion for patients with a history of 2 unsuccessful embryo

transfers

Public title

Evaluation of the effectiveness of intralipid infusion for patients with a history of 2 unsuccessful embryo transfers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have a history of 2 embryo transfers are sampled. Patients who are over 18 to 40 years old and have the necessary criteria for the IVF process All mothers with a history of infertility

Exclusion criteria:

Mothers with dangerous chromosomal abnormalities
Mothers with dangerous abnormalities of antiphospholipid syndrome or positive thrombophilia test
Mothers with endocrine disorders
Mothers with hyperlipidemia disorders
Mothers who were allergic to eggs and their products
Mothers over 40 years old

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

For this study, 80 sealed envelopes were prepared which were divided into two groups A and B and the relevant expert selected one envelope for each patient and the patient was randomly placed in the control or intervention group.

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

Ethics Committee of Mazandaran University of Medical Sciences Sari

Street address

Amir Mazandarani Blvd., Imam Khomeini Hospital, Department of Obstetrics and Gynecology, second floor

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2020-04-29, 1399/02/10

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1399.011

Health conditions studied

1

Description of health condition studied

Recurrent implantation failer

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description

Positive pregnancy test

Timepoint

Two weeks after transfer

Method of measurement

In Imam Khomeini Infertility Center, pregnancy test is performed by ELISA method

Secondary outcomes

1

Description

Record fetal heart rate at 6 weeks of gestation

Timepoint

Six weeks of pregnancy

Method of measurement

sonography

Intervention groups

1

Description

Control group: Intervention group (Intralipid receptor): Intralipid receptor 20% solution in 250 cc of sterile saline, which is administered within two hours. Once between days 4 to 9 of ovarian stimulation and again on day 7 with a positive pregnancy test.

Category

Other

2

Description

Control group: Control group: does not receive interalipid

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Clinic Of Emam Khomaini Hospital

Full name of responsible person

MRs soltani-Mrs rasouli

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Amir Mazandarani Blvd. Imam Khomeini Hospital (RA)
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mr gholami

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Sepideh Peyvandi

Position

Associate Professor, Department of Obstetrics and
Gynecology, Infertility Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Associate Professor of Obstetrics and Gynecology -
Infertility Fellowship

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Leila Mortazavi

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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