

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of Pregnancy Rate in Mixed double embryo transfer (MDET) with Transfer single blastocyst Embryo transfer (SBET) in Recurrent Implantation Failure (RIF)

Protocol summary

Study aim

Comparison of Pregnancy Rate in Mixed double embryo transfer (MDET) with Transfer single blastocyst Embryo transfer (SBET) in Recurrent Implantation Failure (RIF)

Design

the controlled clinical trial, with parallel groups, two-way blind, randomized, on 126 patients. Computer random assignment list produced with PASS software.

Settings and conduct

This is a double-blind randomized clinical trial. Couples with a history of Recurrent Implantation Failure (RIF) who have been referred to Milad Infertility Center during 1300-1400 and meet the inclusion criteria are included in the study. The number of samples is about 56 people in each group. Intervention group: On the day of transfer, one cleavage-stage embryo that thawed the same day and one Blast stage embryo that thawed 2 days before and reached the blast stage are transferred and in control groups, two Blast embryos are transferred

Participants/Inclusion and exclusion criteria

Infertile women (18-42 years) with a history of at least two failed embryo transfers and at least two good-quality embryos have been transferred. • There are at least two 3-day-old freezers with grade 1 or 2 • Normal couple karyotype • Lack of uterine abnormalities and thrombophilic disorders

Intervention groups

Intervention group: On the day of transfer, one cleavage-stage embryo that thawed the same day and one Blast stage embryo that thawed 2 days before and reached the blast stage are transferred

Main outcome variables

Pregnancy confirmed by positive BHCG test two weeks after embryo transfer) and clinical (pregnancy confirmed by transvaginal ultrasound 6 weeks. Ongoing pregnancy : Continued pregnancy up to 20 weeks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181030041503N5**

Registration date: **2021-12-11, 1400/09/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-11, 1400/09/20**

Update count: **0**

Registration date

2021-12-11, 1400/09/20

Registrant information

Name

Malihe Mahmoudinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9878

Email address

mahmoudiniam@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Pregnancy Rate in Mixed double embryo transfer (MDET) with Transfer single blastocyst Embryo transfer (SBET) in Recurrent Implantation Failure (RIF)

Public title

Comparison of pregnancy rates in simultaneous 3 and 5-day embryo transfer with 5-day embryo transfer in patients with a history of recurrent implantation failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women (18-42 years) with a history of at least two failed embryo transfers and at least two good-quality embryos have been transferred. • There are at least two 3-day-old freezers with grade 1 or 2 • Normal couple karyotype • Lack of uterine abnormalities and thrombophilic disorders

Exclusion criteria:

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization -In this randomized clinical trial 126 patients, two groups were randomly assigned. - Method used to generate random allocation sequence by mentioning the name of the software or site used: Computer random assignment list produced with PASS software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this randomized clinical trial 126 patients, two groups were randomly assigned. -Method used to generate random allocation sequence by mentioning the name of the software or site used: Computer random assignment list produced with PASS software.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad university of medical sciences Ethics committee

Street address

Vice chancellor of Research, Mashhad university of Medical Sciences, Mashhad University of Medical Sciences ,University Avenue.Mashhad

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Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-09-22, 1399/07/01

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.126

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N98.3

ICD-10 code description

Complications of attempted introduction of embryo in embryo transfer

Primary outcomes

1

Description

chemical pregnancy rate

Timepoint

2 week after embryo transfer

Method of measurement

BHCG serum

2

Description

The rate of clinical pregnancy

Timepoint

6 weeks after embryo transfer

Method of measurement

Sonography

3

Description

ongoing pregnancy

Timepoint

Continue pregnancy for up to 12 weeks

Method of measurement

Transvaginal ultrasound

Secondary outcomes

1

Description

Rate of miscarriage

Timepoint

Before 20 weeks of pregnancy

Method of measurement

Bleeding and expulsion of the fetus

Intervention groups

1

Description

Intervention group: On the day of transfer, one cleavage-stage embryo that thawed the same day and one Blast stage embryo that thawed 2 days before and reached the blast stage are transferred

Category

Treatment - Other

2

Description

Control group: Two Blast embryos are transferred

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility center

Full name of responsible person

Malihe Mahmoudinia

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Milad Infertility center, Mashhad, Khorasan
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

Maliheh Mahmoudinia

Position

استادیار

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position

Assistant Professor

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Subspecialist

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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

Not applicable

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