

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The pregnancy outcome of sequential embryo transfer compared to blastocyst embryo transfer on patients with repeated implantation failure in frozen and thawed embryo transfer cycles-randomized clinical trial

#### Protocol summary

##### Study aim

Pregnancy outcomes of sequential embryo transfer will be compared with blastocyst transfer in patients with recurrent implantation failure.

##### Design

An controlled, randomized clinical trial with a parallel-group design of 200 patients, enrolled between 2021 and 2023.

##### Settings and conduct

The present study will be performed at Mehr Medical Institute. In the control group, 1 to 3 blastocysts will be transferred into the uterus on day 5 or 6. In the intervention group, two top or good quality embryos will be transferred on day 2 or 3 and then one blastocyst will be transferred on day 5.

##### Participants/Inclusion and exclusion criteria

Participants Patients with recurrent implantation failure  
Inclusion criteria Age less than 40 years History of two or more implantation failure cycles Presence of 3 top and good quality embryos  
Exclusion criteria Recent uterine pathologies that disrupt the pregnancy process  
Preimplantation genetic diagnosis cycles Lack of embryo growth to the blastocyst stage

##### Intervention groups

intervention group- Transfer of 2 top and good quality embryos on the second or third day and transfer of 1 blastocyst on the fifth day  
Control group- Transfer of 1 to 3 blastocysts into the uterus on day 5 or 6

##### Main outcome variables

Biochemical pregnancy; Clinical pregnancy; Implantation rate; Multiple pregnancy rates

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180528039878N4**

Registration date: **2021-12-25, 1400/10/04**

Registration timing: **prospective**

Last update: **2021-12-25, 1400/10/04**

Update count: **0**

##### Registration date

2021-12-25, 1400/10/04

##### Registrant information

###### Name

Marzieh Mehrafza

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3376 4270

###### Email address

dr.Mehrafza@mehrinstitute.org

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-27, 1400/10/06

##### Expected recruitment end date

2023-12-27, 1402/10/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The pregnancy outcome of sequential embryo transfer compared to blastocyst embryo transfer on patients with repeated implantation failure in frozen and thawed

embryo transfer cycles-randomized clinical trial

## Public title

Sequential embryo transfer in repeated implantation failure

## Purpose

Other

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age less than 40 years History of two or more repeated implantation failure cycles Presence of 3 top and good quality embryos

### Exclusion criteria:

Recent uterine pathologies that disrupt the pregnancy process Preimplantation genetic diagnosis cycles Lack of embryo development until the blastocyst stage

## 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: **200**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization will be done using computer software. The list of blocks will be written and numbers will be assigned to them (AABB (1) - ABAB (2) - ABBA (3) - BBAA (4) - BABA (5) - BAAB (6)), then random numbers between one and six ( For example, 1 4 5, etc.) will be select and finally the treatment allocation list based on previous random numbers (AABB, BBAA, BABA, etc.) will be specified.

## 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

Research Ethics Committee of Guilan university of medical sciences

##### Street address

Shahid Siadati Ave, Namjoo St, Rasht, Iran

##### City

Rasht

## Province

Guilan

## Postal code

6694941446

## Approval date

2021-11-10, 1400/08/19

## Ethics committee reference number

IR.GUMS.REC.1400.375

## Health conditions studied

### 1

#### Description of health condition studied

Repeated implantation failure

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Biochemical pregnancy

#### Timepoint

Two weeks after embryo transfer

#### Method of measurement

Blood test

### 2

#### Description

Clinical pregnancy

#### Timepoint

Six weeks after embryo transfer

#### Method of measurement

Ultrasound

### 3

#### Description

Implantation

#### Timepoint

Six weeks after embryo transfer

#### Method of measurement

Ultrasound

### 4

#### Description

Multiple pregnancy

#### Timepoint

During pregnancy

#### Method of measurement

Ultrasound

## Secondary outcomes

## 1

### **Description**

Ongoing pregnancy

### **Timepoint**

Twelve weeks following embryo transfer

### **Method of measurement**

Ultrasound

## 2

### **Description**

Early pregnancy loss

### **Timepoint**

Twelfth week of pregnancy

### **Method of measurement**

Ultrasound

## 3

### **Description**

Late miscarriage

### **Timepoint**

Twelfth to twenty-eighth week

### **Method of measurement**

Ultrasound

## **Intervention groups**

## 1

### **Description**

Intervention group: In consecutive embryo transfer, first; 2 embryos of top and good quality will be transferred on day 2 or 3. The embryos will then be cultured to the blastocyst stage and 1 blastocyst will be transferred on day 5 or 6.

### **Category**

Treatment - Other

## 2

### **Description**

Control group: One to three blastocysts will be transferred on day 5 or 6.

### **Category**

Treatment - Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Mehr medical institute

#### **Full name of responsible person**

Marzieh Mehrafza

#### **Street address**

Mehr Medical Institute, Ershad St, Ansari Blv, Rasht, Iran

#### **City**

Rasht

#### **Province**

Guilan

#### **Postal code**

4178613111

#### **Phone**

+98 13 3376 4270

#### **Email**

marzieh.mehrafza@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Mehr medical institute

#### **Full name of responsible person**

Marzieh Mehrafza

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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**

Mehr medical institute

### **Proportion provided by this source**

100

### **Public or private sector**

Private

### **Domestic or foreign origin**

Domestic

### **Category of foreign source of funding**

*empty*

### **Country of origin**

### **Type of organization providing the funding**

Other

## **Person responsible for general inquiries**

### **Contact**

#### **Name of organization / entity**

Mehr Medical Institute

#### **Full name of responsible person**

Marzieh Mehrafza

#### **Position**

CEO of Mehr medical institute

#### **Latest degree**

Subspecialist

#### **Other areas of specialty/work**

Reproductive Biology

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

Mehr Medical Institute

**Full name of responsible person**

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CEO of Mehr medical institute

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Mehr medical institute

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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