Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effect of sequential embryo transfer (at the stage of cleavage and blastocyst) with embryo transfer only at the blastocyct stage on pregnancy rate in patients with recurrent implantation failure

Protocol summary

Study aim

Comparison of the effect of sequential embryo transfer (in the cleavage and blastocyst stage) with embryo transfer only in the blastocyst stage on the frequency of pregnancy in patients with recurrent implant failure

Design

A clinical trial with a control group was performed on 200 women with a history of recurrent implantation failure with parallel groups, double-blind, randomized, phase 2. Excel software rand function was used for randomization.

Settings and conduct

Women with a history of recurrent implant failure, the first to third day of menstruation under ultrasound and in the absence of follicles above 10 mm and appropriate endometrial thickness, endometrial preparation with estradiol 6 mg daily after receiving estradiol for 9-10 days The patient will have a tvs ultrasound and will add a 400 bd progesterone suppository if the thickness is> 7 mm. In the two-stage embryo transfer group, one embryo is transferred in the cleavage stage on the third day and then on the 5th day, one embryo is transferred in the blastocyst stage. In the control group, both embryos are transferred in the clearance stage on the third day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age less than 45 years, having at least two good three-day-old embryos, women with a history of recurrent implant failure Exclusion criteria: having any uterine abnormalities.

Intervention groups

In the two-stage embryo transfer group, one embryo is transferred in the cleavage stage on the third day and then on the 5th day, one embryo is transferred in the blastocyst stage. All embryos are transferred under ultrasound guidance using a soft catheter. In the control group, both embryos are transferred in the clearance stage on the third day. All embryos are transferred under ultrasound guidance using a soft catheter.

Main outcome variables

pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160722029027N10**
Registration date: **2022-03-14, 1400/12/23**
Registration timing: **retrospective**

Last update: **2022-03-14, 1400/12/23**
Update count: **0**

Registration date

2022-03-14, 1400/12/23

Registrant information

Name

Leila Nazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2271 8000

Email address

nazari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-11-27, 1400/09/06

Actual recruitment start date

2020-12-26, 1399/10/06

Actual recruitment end date

2021-11-29, 1400/09/08

Trial completion date

2021-11-30, 1400/09/09

Scientific title

Comparison of the effect of sequential embryo transfer (at the stage of cleavage and blastocyst) with embryo transfer only at the blastocyct stage on pregnancy rate in patients with recurrent implantation failure

Public title

the effect of sequential embryo transfer on pregnancy rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with a history of recurrent implantation failure Age less than 45 years Have at least two three-day-old fetuses

Exclusion criteria:

Having any uterine abnormalities

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by generating random numbers in Excel software. 1. In a column of Excel we enter 100 samples in each group. 2. In the next column we generate random numbers using the following command: RAND () 3. After sorting the generated random numbers, a random list will be generated according to which people will be assigned to two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blindness will be such that the patient will not know what treatment she will receive. Also, the researcher who records the results will not be aware of the type of treatment applied to the patient

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی شهید بهشتی

Street address

Velenjak, Yaman St, Chamran highway

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Province

Tehran

Postal code

1983969411

Approval date

2022-03-05, 1400/12/14

Ethics committee reference number

IR.SBMU.REC.1400.024

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

clinical pregnancy

Timepoint

5-7 weeks of gestation

Method of measurement

sonography

Secondary outcomes

1

Description

ongoing pregnancy

Timepoint

20 weeks of gestation

Method of measurement

Ultrasonography

2

Description

clinical abortion

Timepoint

20 weeks of gestation

Method of measurement

Ultrasonography

Intervention groups

1

Description

Intervention group: In the two-stage embryo transfer group, one embryo is transferred in the cleavage stage on the third day and then on the 5th day, one embryo is transferred in the blastocyst stage. All embryos are transferred under ultrasound guidance using a soft catheter.

Category

Treatment - Other

2

Description

Control group: Both embryos, under ultrasound guidance using a soft catheter, are transferred to the blastocyst stage on day 5

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility and IVF unit of Talghani hospital

Full name of responsible person

saghar salehpour

Street address

بزرگراه چمران، خیابان یمن، ولنجک، بیمارستان آیت الله طالقانی

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saghar.salehpour2014@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

saghar salehpour

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Shahid Beheshti University of Medical Sciences, Yaman st., Velenjak, Chamran highway

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

zahra razghandi

Position

fellowship of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position
professor

Latest degree
Subspecialist

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Gynecology and Obstetrics

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Person responsible for updating data

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zahra razghandi

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fellowship of infertility

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only information about the main outcome can be shared.

When the data will become available and for how long
Without restriction

To whom data/document is available
All researchers

Under which criteria data/document could be used
With permission from the responsible author

From where data/document is obtainable
With permission from the responsible author

What processes are involved for a request to access data/document
Email to the responsible author

Comments