

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effect of tow embryo transfer in the stage of blastocyst and sequential transfer of a cleavage-a blastocyst embryo on pregnancy outcomes Patients who are candidates for frozen embryo transfer and recurrent implantation failure; a randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of transferring two embryos in the blastocyst stage and sequential transfer of one cleaved blastocyst embryo on pregnancy outcomes in patients who are candidates for frozen embryo transfer and have a history of repeated implantation failure.

Design

The phase 3 clinical trial, with a control group, will be conducted in parallel on 140 patients. The randomization of the samples will be done with Weber's simple randomization method according to the generated list of random numbers. The list of random numbers will be generated using the Random Allocation 1 software by A statistical consultant will be produced.

Settings and conduct

This study is conducted by the clinical trial method in Yazd Research Institute of Reproductive Sciences. The studied and control cases will be selected from among the people with poor ovarian response referring to the infertility clinic who are candidates for assisted reproductive methods. People who meet the criteria for entering the study are divided into two groups: blastocyst and sequential transfer.

Participants/Inclusion and exclusion criteria

Women under 45 years of age with frozen embryos and a history of 2 implantation failures

Intervention groups

Eligible people who have at least 4 frozen embryos are randomly placed in two consecutive transfer groups of one cleavage embryo and one blastocyst embryo and two blast embryos. In the blastocyst group 5 days after the start of progesterone and in the consecutive group once 3 days after the start Progesterone and once 5 days after the start of progesterone, embryo transfer takes place

Main outcome variables

Clinical pregnancy

General information

Reason for update

End of patient admission and end of clinical trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20110509006420N27**

Registration date: **2024-01-27, 1402/11/07**

Registration timing: **prospective**

Last update: **2024-12-23, 1403/10/03**

Update count: **2**

Registration date

2024-01-27, 1402/11/07

Registrant information

Name

Maryam Eftekhar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-30, 1402/11/10

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

2024-02-04, 1402/11/15

Actual recruitment end date

2024-08-05, 1403/05/15

Trial completion date

2024-11-05, 1403/08/15

Scientific title

Comparison of the effect of tow embryo transfer in the stage of blastocyst and sequential transfer of a cleavage- a blastocyst embryo on pregnancy outcomes Patients who are candidates for frozen embryo transfer and recurrent implantation failure; a randomized clinical trial

Public title

Comparison of the effect of tow embryo transfer in the stage of blastocyst and sequential transfer of a cleavage- a blastocyst embryo on pregnancy outcomes Patients who are candidates for frozen embryo transfer and recurrent implantation failure; a randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidates for frozen embryo transfer Failure of more than 2 implants The number of frozen embryos is at least four Women under the age of 45

Exclusion criteria:

Uncontrolled endocrine diseases (diabetes, hyperthyroid and hypothyroid) Egg donation Uncontrolled autoimmune diseases (lupus and rheumatoid arthritis) Severe uterine adenomyosis Sever Asherman Untreated hydrosalpinx

Age

To 45 years old

Gender

Female

Phase

3

Groups that have been masked*No information***Sample size**

Target sample size: 140

Actual sample size reached: 140

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, using the simple randomization method using the Random Allocation1 software (<http://random-allocation software.informer.com\1>) and based on the simple randomization method, the list of samples in the two groups studied by the expert Statistics will be generated. In this software, in order to generate a list of random numbers, first specify the number of groups to be studied as 2 and the total number of samples required as 140 people, and then from the list of sample randomization methods, the method (simple randomization method in parallel group) by considering the same number of samples in the groups. Then a random list will be generated based on the groups and the number of samples in each group. Randomly and after obtaining informed consent by the researcher, they are assigned to two groups. The sealed

envelope method is used for concealment. Then a random list will be generated based on the number of samples in each 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 Yazd reproductive Science Institute- Shahid Sadoghi University of Medical Science

Street address

Yazd Reproductive Sciences Institute, BouAl Ave., Safaeih, Yazd

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Yazd

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Yazd

Postal code

8916877391

Approval date

2024-01-10, 1402/10/20

Ethics committee reference number

IR.SSU.RSI.REC.1402.020

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Clinical pregnancy

Timepoint

4 weeks after embryo transfer

Method of measurement

Sonography

Secondary outcomes

1

Description

Chemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

Through the measurement of BHCG

2

Description

Twin pregnancy

Timepoint

In the 6th week of pregnancy

Method of measurement

Observation of two gestational sacs in vaginal ultrasound

3

Description

The rate of premature abortion

Timepoint

Ten weeks after embryo transfer

Method of measurement

Absence of fetal heartbeat in sonography

4

Description

Ectopic pregnancy

Timepoint

After proving chemical pregnancy

Method of measurement

Not increasing beta hCG titer and not seeing pregnancy sac in vaginal ultrasound

Intervention groups

1

Description

Intervention group: Infertile people who are candidates for frozen embryo transfer with a history of two implantation failures, if their number of embryos is at least 4, after obtaining a written consent, embryo transfer will be done for them consecutively. In this way, in the first stage, an embryo is cleaved and two to three days after the transfer of the first embryo, the transfer of the second embryo is done in the form of a blast.

Category

Treatment - Other

2

Description

Control group: Infertile candidates for frozen embryo transfer with a history of twice implantation failure, if their number of embryos is at least 4, after obtaining a written consent, they will undergo embryo transfer in one step. In this way, two blastocyst embryos will be

transferred to them at the same time.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Reproductive Sciences Institute

Full name of responsible person

Nooshin Hatamizadeh

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Yazd Reproductive Sciences Institute, BouAl Ave., Safaeih, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargouei

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Maryam Eftekhar

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Maryam Eftekhar

Position

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Latest degree

Specialist

Other areas of specialty/work

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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

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

Title and more details about the data/document

All participant data sets are to be shared

When the data will become available and for how long

2 months after the result publication

To whom data/document is available

In order to receive data or other study documents, researchers working in academic and scientific institutions are allowed to apply

Under which criteria data/document could be used

To evaluate the accuracy of the data and use data to complete other researches

From where data/document is obtainable

Yazd Reproductive Sciences Institute, Bouali Ave, Yazd,

Iran

What processes are involved for a request to access data/document

Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its

referral to the security and after completion of the relevant forms, the request is referred to the research experts and then get the data.

Comments