Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Sience Institute- Shahid Sadoghi University of Medical Science
Street address
Yazd Reproductive Sciences Institute, BouAl Ave., Safaeih, Yazd
City
Yazd
Province
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
Street address
Yazd Reproductive Sciences Institute, BouAl Ave., Safaeih, Yazd
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info@Yazd-RSI.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amin Salehi Abargouei
Street address
Bahonar Ave.
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Postal code
8916978477
Phone
+98 35 3726 3733
Email
dvc.research@ssu.ac.ir
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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Maryam Eftekhar

Position

professor

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

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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