

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The pregnancy outcome after blastocyst transfer in women with the history of repeated implantation failure in frozen-thawed cycles

Protocol summary

Study aim

The aim of our study is to compare the pregnancy outcomes of cryopreserved embryos transfer in cleavage with blastocyst stage in patients with the history of recurrent implantation failure.

Design

A non randomized, not blinded, controlled clinical trial with a parallel group design of 100 patients.

Settings and conduct

This non randomized clinical trial will be done at Yazd Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, All women had previously undergone in vitro fertilization (IVF) or intra-cytoplasmic sperm injection (ICSI) with embryo cryopreservation and have the history of repeated implantation failure. The patients are divided into group I (blastocyst group) and group II (cleavage group) at the time of disclosing the sealed envelopes by computerized randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women who will be undergoing in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) with the cryopreserved embryo with history of recurrent implantation failure Exclusion criteria: women with the history of sever endometriosis; endocrine disorders; or hysteroscopic surgery; sever male factor

Intervention groups

Intervention: Transfer of frozen embryo after culture in the medium in blastocyst stage. Control: Transfer of frozen embryo in the cleavage stage.

Main outcome variables

chemical pregnancy; clinical pregnancy

General information

Reason for update

Update based on the latest methodology changes

Acronym

IRCT registration information

IRCT registration number: **IRCT20110509006420N16**

Registration date: **2018-07-30, 1397/05/08**

Registration timing: **prospective**

Last update: **2021-07-01, 1400/04/10**

Update count: **1**

Registration date

2018-07-30, 1397/05/08

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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+98 35182470856

Email address

eftekhar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

2018-08-06, 1397/05/15

Actual recruitment end date

2019-02-04, 1397/11/15

Trial completion date

2019-11-15, 1398/08/24

Scientific title

The pregnancy outcome after blastocyst transfer in women with the history of repeated implantation failure in frozen-thawed cycles

Public title

Blastocyste transfer in patients with history of repeated implantation failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women use frozen embryo transfer History of repeated implantation failure have a minimum of three good quality cryopreserved embryos

Exclusion criteria:

History of severe endometriosis History of severe male factor infertility History of endocrine disorder History of hysteroscopic surgery

Age

To 40 years old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 100

Actual sample size reached: 96

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Infertility Research Center

Street address

Bouali avenue ,Safaieh

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

IR.SSU.RSI.REC.1396.9

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

15 days after embryo transfer

Method of measurement

Blood laboratory kit

2

Description

Clinical pregnancy

Timepoint

3 weeks after positive beta-h Cg

Method of measurement

Observation of fetal heart activity by transvaginal ultrasonography

Secondary outcomes

1

Description

Miscarriage rate

Timepoint

Loss of pregnancy before 20 gestational week

Method of measurement

Absence of fetal heart activity in ultra sound sonography

Intervention groups

1

Description

Intervention group: Thawing will be done at least 2 months after cryopreservation. All embryos in group 1 (blastocyst group) transfer to media and extended culture will be done for 3 days until blastocyst development. Endometrial preparation will be done by estradiol valerate (Aburaihan,Iran) consumption orally at the dose of 6 mg per day from the second day of the menstrual cycle. In day13 of the cycle, an ultrasound examination will be performed. When the endometrial thickness reaches more than 8 mm in diameter, 400 mg vaginal progesterone (Aburaihan,Iran) will be used 2 times daily. Transfer of embryos will be done 3 days after thawing and thawing will be done 2 days after

progesterone injection. Estradiol and progesterone consumption will be continued until the documentation of fetal heart activity by ultrasound.

Category

Treatment - Other

2

Description

Control group: Thawing will be done at least 2 months after cryopreservation. All embryos in group 2 (cleavage group) are transferred to the uterine cavity 2 hours after thawing. Endometrial preparation will be done by estradiol valerate(Aburaihan,Iran) consumption orally at the dose of 6 mg per day from the second day of the menstrual cycle. In day13 of the cycle, an ultrasound examination will be performed. When the endometrial thickness reaches more than 8 mm in diameter, 400 mg progesterone(Aburaihan,Iran) vaginally will be used 2 times in a day. Thawing will be done 2 days after progesterone injection. Estradiol and progesterone consumption is continued until the documentation of fetal heart activity by ultrasound.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Research and Clinical Center for Infertility

Full name of responsible person

Maryam Eftekhari

Street address

Bouali avenue ,Safaieh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Abass Aflatounian

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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 Eftekhari

Position

associated 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

Yazd University of Medical Sciences

Full name of responsible person

Maryam Eftekhari

Position

associated professor

Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
maryam eftekhar
Position
associated professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the privacy of patients

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The study protocol, the statistical analysis map, the clinical study report will be available after publishing of the article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

use in the retrospective study

From where data/document is obtainable

Yazd research and clinical center for infertility

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, request is referred to the research experts and then get the data.

Comments