

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of pregnancy outcome after Transfer of Blastocysts derived from Frozen -Thawed cleavage stage embryos

Protocol summary

Study aim

The aim of this study was to compare implantation and pregnancy rates from vitrified-thawed cleavage-stage embryos which were cultured further to the blastocyst stage versus vitrified-thawed cleavage-stage embryos

Design

134 women had previously undergone in vitro fertilization (IVF) or intra-cytoplasmic sperm injection (ICSI) with embryo cryopreservation in a randomized clinical trial without a control group, parallel trial without blindness, phase 2 were randomly divided into two groups.

Settings and conduct

134 women had previously undergone in vitro fertilization (IVF) or intra-cytoplasmic sperm injection (ICSI) with embryo cryopreservation in Yazd Research and Clinical center for Infertility. The patients were randomly divided into group I (blastocyst group) and group II (cleavage group).

Participants/Inclusion and exclusion criteria

All women had previously undergone in vitro fertilization (IVF) or intra-cytoplasmic sperm injection (ICSI) with embryo cryopreservation. Women with age > 35 years, body mass index (BMI) > 30 kg/m², history of diabetes mellitus, thyroid disease and severe endometriosis were excluded from the study. Oocyte donation cycles were excluded from the study as well.

Intervention groups

group I: embryos were transferred in the blastocyst stage group II: embryos were transferred in the cleavage stage

Main outcome variables

Chemical, Clinical and ongoing pregnancy rates

General information

Reason for update

Updating the trial according to the last changes in methods and adding results

Acronym

IRCT registration information

IRCT registration number: **IRCT201107306420N7**
Registration date: **2011-09-01, 1390/06/10**
Registration timing: **retrospective**

Last update: **2021-04-03, 1400/01/14**

Update count: **2**

Registration date

2011-09-01, 1390/06/10

Registrant information

Name

Maryam Eftekhari

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

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+98 35182470856

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Recruitment status

Recruitment complete

Funding source

Yazd research and clinical center for infertility

Expected recruitment start date

2009-01-01, 1387/10/12

Expected recruitment end date

2010-12-30, 1389/10/09

Actual recruitment start date

2009-01-01, 1387/10/12

Actual recruitment end date

2010-12-30, 1389/10/09

Trial completion date

2011-06-30, 1390/04/09

Scientific title

Evaluation of pregnancy outcome after Transfer of

Blastocysts derived from Frozen –Thawed cleavage stage embryos

Public title

Transfer of Blastocysts in cryopreserved cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

women underwent previously in vitro fertilization (IVF) or intra-cytoplasmic sperm injection (ICSI) with embryo cryopreservation

Exclusion criteria:

History of diabetes mellitus Thyroid disease Severe endometriosis Oocyte donation cycles Women with age > 35 years Body mass index (BMI) > 30 kg/m²

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Actual sample size reached: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

In this trial, 135 infertile women who were candidate for IVF or ICSI were informed about the research design and signed a written consent form. All women were randomly divided into two groups. Randomization was simple, individual using a random number table.

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

Yazd Research and Clinical Center for Infertility, Yazd University of Medical Sciences

Street address

Safaeieh, Bouali Ave

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2011-06-19, 1390/03/29

Ethics committee reference number

927

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

14 days after embryo transfer

Method of measurement

Blood laboratory kit

2

Description

clinical pregnancy

Timepoint

5 weeks after positive beta-hCG

Method of measurement

Observation of fetal heart activity by transvaginal ultrasonography

3

Description

Ongoing pregnancy

Timepoint

12 weeks after embryo transfer

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

Miscarriage rate

Timepoint

Lost of pregnancy before 20 gestational week

Method of measurement

Absence of fetal heart activity in ultra sound sonography

Intervention groups

1

Description

Intervention: Thawing is done at least 2 months after cryopreservation. All embryos in group 1 (blastocyst group) transfer to media and extended culture is done for 3 days until blastocyst development. Endometrial preparation is done by estradiol valerate consumption orally at the dose of 6 mg per day from the second day of menstrual cycle. In day13 of cycle, an ultrasound examination is performed. It is used to assess endometrial thickness. When the endometrial thickness reaches more than 8 mm in diameter, 100 mg progesteron is injected daily. Transfer of embryos is done 3 days after thawing and thawing is done 2 days after progesteron injection. Estradiol and progesterone consumption is continued until the documentation of fetal heart activity by ultrasound .

Category

Treatment - Other

2

Description

Control: Thawing is done at least 2 months after cryopreservation. All embryos in group 2 (cleavage group) are transferred to uterine cavity 2 hours after thawing. Endometrial preparation is done by estradiol valerate consumption orally at the dose of 6 mg per day from the second day of menstrual cycle. In day13 of cycle, an ultrasound examination is performed. It is used to assess endometrial thickness. When the endometrial thickness reaches more than 8 mm in diameter, 100 mg progesteron is injected daily. Thawing is done 2 days after progesteron 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 Eftekhar

Street address

Bouali ave

City

Yazd

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Yazd

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8916877391

Phone

+98 35 3824 7085

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd research and clinical center for infertility

Full name of responsible person

Dr.Abbas Aflatoonian

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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 research and clinical center for infertility

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

YAazd Research and Clinical Center for Infertility

Full name of responsible person

Maryam Eftekhar

Position

Gynecologist,MD

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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Position

Gynecologist,MD

Latest degree

Specialist

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Other areas of specialty/work

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Web page address

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

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

A journal in which the results are published

Under which criteria data/document could be used

Submission of an official application via the agent that is legally incharge

From where data/document is obtainable

Yazd Reproductive Sciences Institute, Bouali Ave, Yazd, Iran. 983538247085 eftekharmaryam@yahoo.com

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

2 months after application

Comments