Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Clinical trial comparing pregnancy rate between fresh and frozen embryo transfer cycles in women with endometriosis: a pilot Study

Protocol summary

Summary

Objectives: endometriosis is a common condition that affects 10–15% of all women women during the reproductive years. Endometriosis is a major cause of infertility and may be present with no symptoms. In vitro fertilization (IVF) offers the highest chance of pregnancy for subfertile women with endometriosis. The aim of our study is to evaluate the reproductive outcomes of frozen-thawed embryo transfers (ET) cycles compared to fresh embryo transfer cycles, in women with endometriosis. Design: in this randomized controlled pilot study a total of 60 infertile women with endometriosis who will be referred to Royan Institute will be recruited. Setting and conduct: all subjects underwent conventional controlled ovarian stimulation using a ultra-long protocol. After puncture the patients will be divided in to two groups of study and control. In the study group embryos will be frozen for 2 months. Gonadotropin also is used for 2 months in order to prepare the endometrium. Then hormonal replacement therapy will be performed and followed by frozen-thawed embryo transfer. In control group, the fresh embryos will be transferred. Participants including major eligibility criteria: women with well-known predisposing factors for implantation failure such as thrombophilia, underlying immune conditions, uterine malformation (i.e. didelphys, septate, bicornuate or hypoplastic uterus); parental chromosomal abnormalities; severe male factor infertility; cancelled cycles which did not result in embryo transfers and women with frozen embryos in which their cycles had been canceled due to thin endometrial thickness. Intervention: The women will be randomly divided into two groups of frozen-thawed embryo transfer and fresh embryo transfer. Main outcome measures: Clinical pregnancy rate outcome will be compared between 2 groups. To confirm the pregnancy, the patients will be tested for serum β-hCG, 14 days after embryo transfer. Vaginal sonography will be done 2 weeks after the positive result of pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608171141N21**
Registration date: **2016-08-26, 1395/06/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-26, 1395/06/05

Registrant information

Name
Kiandokht Kiani
Name of organization / entity
Royan Institute
Country
Iran (Islamic Republic of)
Phone
+98 21 2230 7960
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Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2014-01-30, 1392/11/10

Expected recruitment end date

2015-08-01, 1394/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial comparing pregnancy rate between fresh and frozen embryo transfer cycles in women with endometriosis: a pilot Study

Public title
Comparison of pregnancy rate between fresh and frozen embryo transfer cycles in women with endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: infertile patients with endometriosis; age ≤ 35 years; at least one endometrioma diagnosed by sonography or confirmed by laparoscopy; history of one failed in vitro fertilization failure (IVF). Exclusion criteria: women with well-known predisposing factors for implantation failure such as thrombophilia, underlying immune conditions, uterine malformation (i.e. didelphys, septate, bicornuate or hypoplastic uterus); parental chromosomal abnormalities; severe male factor infertility; cancelled cycles which did not result in embryo transfers; women with frozen embryos in which their cycles had been canceled due to thin endometrial thickness.

Age
To **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
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
Royan Institute

Street address
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City
Tehran

Postal code

Approval date
2012-09-25, 1391/07/04

Ethics committee reference number
EC/91/1085

Health conditions studied

1

Description of health condition studied
Endometriosis of ovary

ICD-10 code
N80.1

ICD-10 code description
Endometriosis of ovary

Primary outcomes

1

Description
Clinical pregnancy rate

Timepoint
4-6 weeks after embryos transfer (ET)

Method of measurement
Vaginal sonography

Secondary outcomes

1

Description
Implantation rate

Timepoint
4-6 weeks after embryos transfer (ET)

Method of measurement
Vaginal sonography

2

Description
Ongoing pregnancy rate

Timepoint
Pregnancy after 12 weeks of gestation

Method of measurement
Vaginal sonography

3

Description
Miscarriage rate

Timepoint
Abortion before 12 weeks of gestation

Method of measurement
Vaginal sonography

Intervention groups

1

Description
Intervention/ Control: In the intervention group، embryos will be frozen for 2 months. Gonadotropin also is used for 2 months in order to prepare the endometrium. Then hormonal replacement therapy will be performed and followed by frozen-thawed embryo transfer.
Category
Treatment - Other

2

Description
Intervention/ Control: In control group, the fresh embryos will be transferred.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institute
Full name of responsible person
Nadia Jahangiri
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Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Royan Institute
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Full name of responsible person
Nadia Jahangiri
Position
MS of midwifery / principal investigator
Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty