

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of pregnancy outcomes in 3- and 5-day frozen embryo transfer cycles with blastocysts in normoresponder women

Protocol summary

Study aim

Comparison of pregnancy outcomes in 3- and 5-day frozen embryo transfer cycles with blastocysts in normoresponder women

Design

A controlled, double-blind, randomized, parallel-group, on 148 patients. Randomization using a computerized random allocation sequence (<https://www.sealedenvelope.com/>).

Settings and conduct

Double-blind, randomized clinical trial. Infertile women referred to the Milad Infertility Center between 1402-1404 who met the inclusion criteria. Sample size is calculated as 74 in each group. On the transfer day, in the intervention group, a 5-day embryo and in the control group, 3- and 5-day embryos are transferred.

Participants/Inclusion and exclusion criteria

Infertile women (18-41 years), normal uterine cavity, normal ovarian response to stimulation, women undergoing infertility treatment with IVF or microinjection and having at least 3 frozen embryos, no history of endometriosis or endocrine disorders and hysteroscopic surgery, no severe male factor infertility, no poor ovarian response or excessive ovarian response. Exclusion criteria: Cervical insufficiency, endometrial thickness < 7 mm on the day of embryo transfer, and unwillingness to continue the study.

Intervention groups

Ovarian stimulation is performed using 2 protocols (Agonist or Antagonist). When at least three follicles reach 17 mm, 10000 units of HCG are administered and 36 h later, oocyte retrieval is performed. Embryos are frozen in the cleavage phase for three days. Endometrial preparation is performed with three regimens (letrozole, hormone therapy with estradiol valerate, or a planned regimen). On transfer day, in the intervention group, a 5-day embryo and in the control group, a 3-day embryo and a 5-day embryo are transferred by catheter (Cook, Australia).

Main outcome variables

Chemical pregnancy rate, Implantation rate and clinical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201121049457N3**

Registration date: **2026-02-12, 1404/11/23**

Registration timing: **prospective**

Last update: **2026-02-12, 1404/11/23**

Update count: **0**

Registration date

2026-02-12, 1404/11/23

Registrant information

Name

Malihe Amirian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

Email address

amirianm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2026-04-21, 1405/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty	envelopes, which are sorted and numbered according to the sequence generated by the software, and patients are assigned to the intervention or control group based on the card inside the envelope. With this concealment method, neither the patient nor the statistical consultant knows the type of treatment being received, and the statistical consultant, when analyzing the data, sees the type of treatment in coded form (A and B).
Trial completion date empty	
Scientific title Comparison of pregnancy outcomes in 3- and 5-day frozen embryo transfer cycles with blastocysts in normoresponder women	
Public title Comparison of pregnancy outcomes in 3- and 5-day frozen embryo transfer cycles with blastocysts in normoresponder women	
Purpose Treatment	Placebo Not used
Inclusion/Exclusion criteria Inclusion criteria: Infertile women (18-41 years old) Normal uterine cavity Normal ovarian response to stimulation Women undergoing infertility treatment with IVF or microinjection and having at least 3 frozen embryos No history of endometriosis or endocrine disorders and no hysteroscopic surgery No severe male factor infertility No poor ovarian response (less than or equal to 3 oocytes) or excessive ovarian response (more than 20 oocytes) Exclusion criteria: Cervical insufficiency Endometrial thickness less than 7 mm on the day of embryo transfer Unwillingness to continue the study	Assignment Parallel
Age From 18 years old to 41 years old	Other design features
Gender Female	Secondary Ids empty
Phase N/A	Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Mashhad University of Medical Sciences Street address Mashhad university of Medical Sciences City Mashhad Province Razavi Khorasan Postal code 9138813944
Groups that have been masked • Participant • Data analyser	Approval date 2025-11-22, 1404/09/01 Ethics committee reference number IR.MUMS.REC.1404.281
Sample size Target sample size: 148	Health conditions studied 1 Description of health condition studied Infertility ICD-10 code N97 ICD-10 code description Female infertility
Randomization (investigator's opinion) Randomized	Primary outcomes 1 Description chemical pregnancy rate Timepoint 2 week after embryo transfer Method of measurement BHCG serum
Randomization description Random assignment of eligible subjects to the study will be performed by an individual who is independent of the research team and has no involvement in the treatment process, participant follow-up, data collection, or recording. After the subjects have been identified as eligible for the study and their informed consent has been confirmed, they will be assigned to the study groups using a block randomization method (blocks of 4, 37 blocks). Randomization will be performed using a computerized random assignment sequence (https://www.sealedenvelope.com/).	
Blinding (investigator's opinion) Double blinded	
Blinding description To conceal, cards are prepared that identify the intervention and control groups (for example, A on the card indicates the intervention group and B indicates the control group). Then these cards are placed in opaque	

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Description

clinical pregnancy rate

Timepoint

6 weeks after embryo transfer

Method of measurement

Sonography

Secondary outcomes

1

Description

Abortion rate

Timepoint

Before 20 weeks of pregnancy

Method of measurement

Bleeding and expulsion of the fetus

Intervention groups

1

Description

Intervention group: On the transfer day, a 5-day embryo is transferred.

Category

Treatment - Other

2

Description

Control group: On the transfer day, 3- and 5-day embryos are transferred.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility Center

Full name of responsible person

Malihe Amirian

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Milad Infertility Center

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Amirian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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