

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Intramuscular Injection of Triple Doses of Human Chorionic Gonadotropin in Frozen Embryo Transfer Cycles

Protocol summary

Study aim

Comparison of live births rate in frozen embryo transfer cycles with and without intramuscular injection of human chorionic gonadotropin.

Design

A randomized clinical trial with control group, open label, two arm parallel group design of 100 patients. Randomization is performed using a computer-generated random assignment schedule for each patient. Sealed and numbered envelopes are used to conceal the treatment allocation until randomization.

Settings and conduct

Female infertility Clinic of ROYAN institute.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Infertile women candidates for frozen embryo transfer; Age 20-40 years; Body Mass Index under than 30 Kg/m²; Having at least three good quality embryos. Conditions for not entering the study: Women with hematologic and autoimmune disorders; Couples with chromosomal and genetic abnormalities; Women with uterine anomalies; Women with uterine and ovaries surgical history; Women with endometriosis and adenomyosis; Women with hydrosalpinx; Women with uterine fibroids; Women with history of recurrent abortion or recurrent implantation failure; Severe male factor infertility (azoospermia); Embryo donation cycle; Endometrial thickness less than 8 millimeter on the day of embryo transfer.

Intervention groups

Intervention group: The group of frozen embryo transfer with intramuscular injection of human chorionic gonadotropin. Control group: The group of frozen embryo transfer without intramuscular injection of human chorionic gonadotropin.

Main outcome variables

Live births rate

General information

Reason for update

Acronym

FET-HCG

IRCT registration information

IRCT registration number: **IRCT20080831001141N32**

Registration date: **2020-12-28, 1399/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-28, 1399/10/08**

Update count: **0**

Registration date

2020-12-28, 1399/10/08

Registrant information

Name

Kiandokht Kiani

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2230 7960

Email address

kiandokht.kiani@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-01, 1399/04/11

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Intramuscular Injection of Triple Doses of Human Chorionic Gonadotropin in Frozen Embryo Transfer Cycles

Public title

Intramuscular Injection of Human Chorionic Gonadotropin in Frozen Embryo Transfer Cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women candidates for frozen embryo transfer
Age 20-40 years Body Mass Index under than 30 Kg/m²
Having at least three good quality embryos

Exclusion criteria:

Women with hematologic and autoimmune disorders
Couples with chromosomal and genetic abnormalities
Women with uterine anomalies Women with uterine and ovaries surgical history Women with endometriosis and adenomyosis Women with hydrosalpinx Women with uterine fibroids Women with history of recurrent abortion or recurrent implantation failure Severe male factor infertility (azoospermia) Embryo donation cycle
Endometrial thickness less than 8 millimeter on the day of embryo transfer

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method is designed by epidemiologist using STATA software version 13 and the number of blocks considered is 6. The random allocation list for patients is solely available to the epidemiologist. In order to hide the random allocation process, a total of 200 envelopes are prepared, and only the methodologist has been aware of table of random numbers. When the doctor declared the patient's eligibility, the methodologist provided the doctor with the envelope. The group will be selected and based on the type of group mentioned in the envelope.

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 Royan Institute

Street address

Royan Institute, Number 12, East Hafez Avenue, Banihashem Street, Resalat Highway.

City

Tehran

Province

Tehran

Postal code

148- 16635

Approval date

2020-06-30, 1399/04/10

Ethics committee reference number

IR.ACECR.ROYAN.REC.1399.015

Health conditions studied

1

Description of health condition studied

Implantation of embryo

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Live birth rate; live birth is defined in which a live fetus is delivered beyond 20 completed weeks of gestational.

Timepoint

Only once; at least 20 weeks after embryo transfer.

Method of measurement

Clinical information.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group of frozen embryo transfer with intramuscular injection of human chorionic gonadotropin. In this group, endometrial preparation for embryo transfer will be through the standard protocol using a gonadotropin-releasing hormone agonist. Patients receive 5,000 IU of human chorionic gonadotropin by intramuscular injection, 72 hours before embryo transfer, on the day of embryo transfer, and 72 hours after embryo transfer.

Category

Treatment - Other

2**Description**

Control group: The group of frozen embryo transfer without intramuscular injection of human chorionic gonadotropin. In this group, endometrial preparation for embryo transfer will be through the standard protocol using a gonadotropin-releasing hormone agonist. Embryo transfer will be done without human chorionic gonadotropin intramuscular injection.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility Center of ROYAN

Full name of responsible person

Mehri Mashayekhy

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Royan Institute, Number 12, East Hafez Avenue, Banihashem Street, Resalat Highway.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

ROYAN Institute

Full name of responsible person

Parvaneh Afsharian

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pafshar@royaninstitute.org

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

ROYAN Institute

Full name of responsible person

Mehri Mashayekhy

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

ROYAN Institute

Full name of responsible person

Mehri Mashayekhy

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Clinical study report (published article)

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Available to the public.

Under which criteria data/document could be used

Scientific use by citing the source.

From where data/document is obtainable

Dr. Mehri Mashayekhy Email:

dr.mashayekhy@yahoo.com

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

Request via e-mail

Comments

Person responsible for updating data

Contact

Name of organization / entity

ROYAN Institute

Full name of responsible person

Mehri Mashayekhy

Position

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