

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of intrauterine injection of human gonadotropin (HCG) on the outcome of embryo transfer cycles in women

Protocol summary

Study aim

Assessing the effect of intrauterine injection of human gonadotropin on the outcome of embryo transfer cycles

Design

Randomized clinical trial with control group with parallel groups design of 150 patients in each group

Settings and conduct

The present study is a randomized clinical trial designed on 300 women referred to Yas Infertility Center in 1398. The available sampling method will be used to select the samples. The study sample will be assigned to one of two groups using random allocation by block randomization at a ratio of 1: 1: Intervention group will receive 500 units of HCG prior to embryo transfer by intrauterine injection and The control group will not receive any intervention before embryo transfer. Embryo transfer will be performed on day 2 or 3 after oocyte harvest. In control group, embryo transfer will be performed without intrauterine injection of HCG. A pregnancy test will be performed 2 weeks after the embryo transfer and 3 weeks after a positive pregnancy test. An ultrasound examination will be performed to see the number and location of the pregnancy sac and confirm the fetal heart rate.

Participants/Inclusion and exclusion criteria

Women with primary infertility who have had at least one fetal transfer and have at least one Grade A or B frozen fetus and are younger than 40 years.

Intervention groups

The intervention group will receive 500 units of HCG prior to embryo transfer via intrauterine injection and the control group will receive no intervention before embryo transfer.

Main outcome variables

Definitive pregnancy rate, Chemical pregnancy rate, Clinical pregnancy rate, Ectopic pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200213046475N1**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **prospective**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Mahshid Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6649 2271

Email address

s_khazaeii@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intrauterine injection of human gonadotropin (HCG) on the outcome of embryo transfer cycles in women

Public title

Effect of intrauterine injection of human gonadotropin (HCG) on the outcome of embryo transfer cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with primary infertility who have had at least one fetal transfer At least have one Grade A or B frozen embryo

Exclusion criteria:

Age over 40 years BMI over 30 kg/m² Infertility with severe male cause such as azoospermia Uterine myoma or history of myomectomy Endometriosis Grade 3 and 4 Hydrosalpingitis The duration of freezing of the fetus more than 2 years

Age

To 40 years old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 300

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation by balanced blocked randomization with the 1:1 proportion of intervention group to control group

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 Tehran University of Medical Sciences

Street address

Poorsina street

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2020-02-04, 1398/11/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.872

Health conditions studied

1

Description of health condition studied

Primary infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Pregnancy rate

Timepoint

2 weeks after embryo transfer

Method of measurement

Sonography

Secondary outcomes

1

Description

Abortion rate

Timepoint

Before the 20th week of pregnancy

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: 40 µl of tissue culture medium containing 500 units of HCG by intrauterine injection

Category

Treatment - Drugs

2

Description

Control group: Embryo transfer without intrauterine injection of HCG

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas infertility center

Full name of responsible person

Mahshid Karimi

Street address

Poursina

City

Tehran

Province

Tehran

Postal code

1417653911

Phone

+98 21 8890 4172

Email

mkarimi6471@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Poorsina

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mahshid Karimi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Karim Khan Zand Street

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6649 2271

Fax

Email

s_khazaeii@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahshid Karimi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Karim Khan Zand Street

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6649 2271

Fax

Email

s_khazaeii@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

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Mahshid Karimi

Position

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Gynecology and Obstetrics

Street address

Karim Khan Zand Street

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Phone

+98 21 6649 2271

Fax**Email**

s_khazaeii@yahoo.com

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

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

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