

# 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**

Poursina

**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

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**Province**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

### 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

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**Phone**

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**Fax****Email**

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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**

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