

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation effect of intrauterine injection of human chorionic gonadotropin before embryo transfer on implantation rate and pregnancy rate in frozen cycles on IVF/ICSI

Protocol summary

Summary

The aim of this study will be to investigate the value of intrauterine HCG injection before embryos transfer in improvement of implantation and pregnancy rates in cycles of IVF/ ICSI. From November 2017 through December 2017 we will evaluated 300 patients undergoing IVF/ICSI at our center for treatment of infertility . Patients will be divided into tow groups using a random numbers table. In all patients in time of monitoring when at least three follicles 18 mm to be seen on ultrasound, 10,000IU units HCG will be injected. 36 hours after puncturing oocytes, IVF or ICSI will be performed. Embryo transfer (ET) will be performed 48-72 hours after. In the study groups, injecting HCG intrauterine, Culture media will added to a vial HCG 500IU and will be get HCG dilution requirement(500IU unit)for intrauterine injection. In the second or third day after the oocyte pickup ,after inserting a speculum and view the cervix in lithotomy position and after will passed the internal cervical OS, 40 microliter of tissue culture medium containing 500IU of hCG through a soft catheter(Cook) will injected intrauterine. Approximately 10 minutes after intrauterine HCG injection, between 2-3 embryo through another soft catheter(Cook) embryo transfer (ET) will be performed. In the control group, ET will performed without the intrauterine hCG injection. In control group between 2-3 embryo through of Cook catheter embryo transfer (ET) will be performed. For luteal phase support progesterone 100 mg intramuscular injection will used . primary outcomes: Chemical pregnancy, Clinical pregnancy , Implantation rates.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041733486N1**

Registration date: **2017-10-13, 1396/07/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-13, 1396/07/21

Registrant information

Name

Zohreh Ziaee

Name of organization / entity

Tehran university

Country

Iran (Islamic Republic of)

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+98 21 2205 0129

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ziaee-z@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor Of Research, Tehran University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation effect of intrauterine injection of human

chorionic gonadotropin before embryo transfer on implantation rate and pregnancy rate in frozen cycles on IVF/ICSI

Public title

Evaluation effect of human chorionic gonadotropin on pregnancy outcome in infertile patients

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria:patients with a history of utrine surgery such as myomectomy;Patients with a history of recurrent miscarriage;Patients with known hydrosalpinx;Patients with endometriosis and endometroma;Patients with history of RIF(>3);Patients >40 years ;Inclusion criteria:All patients under age 40 years who refer to Omid fertility centre and shariati hospital who suffered from infertility.

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: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Number21, Daneshgah St, Valiasr Ave, Tehran, Iran

City

Tehran

Postal code

1416753955

Approval date

2017-02-07, 1395/11/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.1660

Health conditions studied

1

Description of health condition studied

IVF

ICD-10 code

Z31.2

ICD-10 code description

In vitro fertilization Admission for harvesting or implantation of ova

2

Description of health condition studied

ICSI

ICD-10 code

Z31.1

ICD-10 code description

Artificial insemination

3

Description of health condition studied

Infertility

ICD-10 code

N98.3

ICD-10 code description

Complications of attempted introduction of embryo in embryo transfe

Primary outcomes

1

Description

Embryo implantation

Timepoint

4 weeks after transfer

Method of measurement

Sonography

2

Description

chemical pregnancy

Timepoint

2 weeks after transfer

Method of measurement

pregnancy test(BHCG test)

3

Description

clinical pregnancy

Timepoint

4-5 weeks after emberyo transfer

Method of measurement

observation of fetal heart activity by transvaginal ultrasonography

Secondary outcomes

1

Description

Abortion

Timepoint

2-4 weeks after transfer

Method of measurement

By sonography, clinical finding, pregnancy test

2

Description

ectopic pregnancy

Timepoint

4 weeks after transfer

Method of measurement

by sonography, pregnancy test

Intervention groups

1

Description

Control group: The second group (n 130) did not receive the administration of 500 IUhCG.

Category

Other

2

Description

Interventional group (n 130) was injected with 500 IU of intrauterine hCG before embryo transfer.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Ziaee Zohreh OB/GYN Resident

Street address

Shariati Hospital, North Kargar St, Tehran, Iran

City

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2

Recruitment center

Name of recruitment center

Omid Fertility Clinic

Full name of responsible person

Ziaee Zohreh OB/GYN Resident

Street address

Number 2, Dead end bazargan, Shahbaznejad Alley, Aghaee St, Niavaran Ave, Tehran, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor Of Research, Tehran University of Medical Sciences

Full name of responsible person

Mrs Kermani

Street address

Number 21, Daneshgah St, Valli-e Asr Ave, Tehran, Iran

City

Tehran

Grant name

None

Grant code / Reference number

None

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

Yes

Title of funding source

Vice Chancellor Of Research, Tehran University of Medical Sciences

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

Name of organization / entity

Tehran University

Full name of responsible person

Ziaee Zohreh

Position

OB/GYN Residency

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