

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the effect of intrauterine injection of human chorionic gonadotropin (HCG) before embryo transfer (ET) on pregnancy outcomes in assisted reproductive cycles (IVF / ICSI)

Protocol summary

Study aim

Determining the effect of intrauterine injection of human chorionic gonadotropin (HCG) on pregnancy outcomes in IVF / ICSI cycles

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 per 100 patients. With randomize all location software, individuals are assigned to two intervention and control groups, and matching both groups will be done based on age / body mass index and antimullerian hormone level.

Settings and conduct

Patients are randomly assigned to the intervention and control groups. Both groups are assimilated in terms of "BMI" AMH. It is injected 15 minutes before transfer to the lithotomy position and after the speculum is placed, and it is not injected in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hip women under 40 years of age who undergo the necessary treatment protocols for IVF / ICSI are endocrine candidates for grade A or B embryos.
Exclusion criteria: Azoospermia through sperm test / History of uterine surgery through history / Severe endometriosis through history Ultrasound findings / Hydrosalpinx through ultrasound / Hysterosalpingography / Sub endocrine disorders such as diabetes mellitus / More repeated failures equal to 3 times the history

Intervention groups

In the intervention group, a 5000-unit HCG vial with Karma brand is mixed with 0.4 ml of embryo glue and 40 µl of which is equivalent to 500 units of HCG.

Main outcome variables

AMH; Chemical pregnancy; Implantation; Cilinical pregnancy; Ongoing pregnancy; Number of embryos transferred per cycle; Type of embryo transferred; Follicle size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160703028756N7**

Registration date: **2021-10-16, 1400/07/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-16, 1400/07/24**

Update count: **0**

Registration date

2021-10-16, 1400/07/24

Registrant information

Name

Elham Naghshineh

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 7085

Email address

naghshineh@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-29, 1400/06/07

Expected recruitment end date

2021-11-28, 1400/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of intrauterine injection of human chorionic gonadotropin (HCG) before embryo transfer (ET) on pregnancy outcomes in assisted reproductive cycles (IVF / ICSI)

Public title

The effect of intrauterine injection of human chorionic gonadotropin before embryo transfer on pregnancy outcomes in assisted reproductive cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hip women under the age of 40 who have undergone IVF / ICSI treatment protocols are endocrine candidates for grade A or B embryos.

Exclusion criteria:

Azoospermia through sperm testing History of uterine surgery through history Severe endometriosis through history and ultrasound findings Hydrosalpinx by ultrasound or hysterosalpingography Endocrine disorders such as diabetes thyroid via blood biochemistry test History of operative hysteroscopy History of recurrent miscarriages More repeated failures equal to 3 times in the history

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

After the approval of the ethics committee and performing PCRcovid19 test (due to the unknown nature of Covid virus and its possible effects on fertility results and IVF cycles) from all patients before entering the operating room for embryo transfer "and in case of negative Covid PCR test" women were randomly divided Both groups are assimilated in terms of "BMI" AMH. Speculum is injected and is not injected in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug will be injected in the case group by an infertility specialist and in these cases the patient is unaware of which group he is in, given that the injection is given intrauterine and in a lithotomy position and the patient feels pain during the injection. Will not notice this process, on the other hand, after the embryologist injection, the fetus will be transferred while the patient is

in the control group or is unaware of the case.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib St., Isfahan University of Medical Sciences and Health Services

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-08-29, 1400/06/07

Ethics committee reference number

IR.MUI.MED.REC.1400.414

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Follicle size

Timepoint

During embryo transfer and one week after embryo transfer

Method of measurement

sonography

2

Description

Type of embryo transferred

Timepoint

Method of measurement

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3

Description

Number of embryos transferred per cycle

Timepoint

Patient cycle

Method of measurement

Laboratory

4

Description

AMH

Timepoint

Before embryo transfer

Method of measurement

Laboratory

Secondary outcomes

1

Description

Ongoing pregnancy

Timepoint

After embryo transfer

Method of measurement

Question from the patient

2

Description

Clinical pregnancy

Timepoint

After embryo transfer

Method of measurement

Question from the patient

3

Description

Chemical pregnancy

Timepoint

After embryo transfer

Method of measurement

Question from the patient

Intervention groups

1

Description

Intervention group: In the intervention group, a 5000-unit vial of Karma brand with Karma brand is mixed with 0.4 ml of embryo glue and 40 µl of which is equivalent to 500 units of HCG is injected into the uterus through an IUI catheter within 15 minutes before transfer to the erectile position and injected into the orthopedic position.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Dr. Beheshti Hospital, Isfahan

Full name of responsible person

Elham Naghshineh

Street address

Felezzy81848 bridge - Ostad Motahhari street

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Email

naghshineh@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Elham Naghshineh

Street address

Hezar Jarib St., Isfahan University of Medical Sciences and Health Services

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Elham Naghshineh

Position

Associate Professor, Gynecologist, Infertility

Fellowship, Faculty

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Elham Naghshineh

Position

Associate Professor, Obstetrician and Gynecologist,

Infertility Fellowship, Faculty Member, Iran Uni

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

Esfahan University of Medical Sciences

Full name of responsible person

Elham Naghshineh

Position

Associate Professor, Obstetrician, Infertility

Fellowship, Faculty Member

Latest degree

Specialist

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

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