Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the effect of intrauterine injection of human chorionic gonadotropin (hCG) before embryo transfer on the implantation and pregnancy rates in the intracytoplasmic sperm injection (ICSI) method among patients who referred to Avicenna Infertility Clinic during 2013-2014.

Protocol summary

Summary

(1) Objectives: Comparing implantation and pregnancy rates between the treatment and control groups (2) Design: Double-blind randomized controlled trial (3) Setting and Conduct: Participants are randomly assigned to the treatment and control groups. After the study intervention, the two groups are compared in terms of implantation and pregnancy rates. Data are gathered via a study form and are analysed using SPSS software.. (4) Participants: All ICSI candidates referring to Avicenna Infertility Clinic during 2013-14 aged between 20 and 40 yr with infertility due to male factor, PCO, or with unknown cause without previous successful or failed IVF/ICSI or any significant abnormality in the uterus and reproductive system. (5) Intervention: Intrauterine injection of 500 units HCG dissolved in 40 microliter culture media in the treatment group and only 40 microliter culture media in the control group immediately before embryo transfer. (6) Main outcome measures: Implantation rate and pregnancy rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060913605N1**
Registration date: **2013-08-18, 1392/05/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-18, 1392/05/27

Registrant information

Name
Bita Badehnoosh
Name of organization / entity
Avicenna Infertility Clinic
Country
Iran (Islamic Republic of)
Phone
+98 21 23519
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b.badehnoosh@avicenna.ac.ir

Recruitment status

Recruitment complete

Funding source
Avicenna Infertility Clinic

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2014-03-17, 1392/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of intrauterine injection of human chorionic gonadotropin (hCG) before embryo transfer on the implantation and pregnancy rates in the intracytoplasmic sperm injection (ICSI) method among patients who referred to Avicenna Infertility Clinic during 2013-2014.

Public title

The effect of intrauterine injection of human chorionic gonadotropin (hCG) before embryo transfer on the implantation and pregnancy rates in the intracytoplasmic sperm injection (ICSI)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: age between 20 and 40 yr; infertility due to male factor, PCO, or with unknown cause; informed consent from couples; obtaining high quality embryos Exclusion criteria: azoospermia or severe oligoasthenoteratospermia; previous successful or failed IVF/ICSI; myometrium or any uterus abnormality; previous myomectomy; moderate to severe endometriosis; hydrosalpynx; obtaining more than 20 ovums or probable OHSS; nonadherence to the study protocol

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **121**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Explanation regarding blinding of the study: It is evident that researcher is aware of the intervention but who performs the intervention is unaware and is not from research group. Moreover, according to informed consent, participants should be informed that may receive a certain drug but they are not aware of their group. All steps of the study are similar for both groups except that controls receive only culture media instead of hCG plus culture media in the treatment group; neither the patient nor the operator is aware of the content of the instillation. It seems there is no problem regarding the blindness of the study.

Secondary Ids

1

Registry name

No secondary ID

Secondary trial Id

No secondary ID

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Avicenna Infertility Clinic

Street address

No 97, Yakhchal - Shariati Junction, Shariati St.

City

Tehran

Postal code

19615-1177

Approval date

2013-06-25, 1392/04/04

Ethics committee reference number

92/1556

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

Z31.2

ICD-10 code description

In vitro fertilization

Primary outcomes

1

Description

Implantation rate

Timepoint

2 weeks after embryo transfere

Method of measurement

Serum level of B-hCG (mIU/ml) based on laboratory report

2

Description

Pregnancy rate

Timepoint

3 weeks after positive serum B-hCG

Method of measurement

Detection of gestational sac by ultrasonographic exam

Secondary outcomes

1

Description

Serum level of B-hCG

Timepoint

2 weeks after embryo transfere

Method of measurement

mIU/ml based on laboratory report

Intervention groups

1

Description
Intrauterine injection of hCG and embryo transfer in the treatment group: immediately before embryo transfer, 500 IU of hCG dissolved in 40 microliter culture media is instilled into the uterine cavity using an insemination catheter. After that, embryos are transferred into the uterine cavity.
Category
Treatment - Other

2

Description
Intrauterine injection of placebo and embryo transfer in the control group: immediately before embryo transfer only 40 microliter culture media is instilled into the uterine cavity using an insemination catheter. After that, embryos are transferred into the uterine cavity.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Avicenna Infertility Clinic
Full name of responsible person
Dr Bita Badehnoosh
Street address
No 97, Yakhchal - Shariati Junction, Shariati St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Avicenna Infertility Clinic
Full name of responsible person
Dr Mohammad Mahdi Akhondi
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No. 97, Yakhchal-Shariati Junction, Shariati St.
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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
Avicenna Infertility Clinic
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
Avicenna Infertility Clinic
Full name of responsible person
Dr Bita Badehnoosh
Position
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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