

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of intrauterine human chorionic gonadotropin injection before embryo transfer on the implantation and pregnancy rate in infertile patients: A randomized clinical trial

Protocol summary

Study aim

This study aims to investigate the effect of intrauterine human chorionic gonadotropin injection before embryo transfer on the implantation and pregnancy rate in infertile women.

Design

Clinical trial with control group, parallel, phase 2 on 159 patients (n=53/each group), random number table was used for randomization.

Settings and conduct

159 participants undergoing In vitro Fertilization/ Intracytoplasmic Sperm Injection (IVF/ICSI) with an antagonist protocol referring to Yazd Research and Clinical Center for infertility will be evaluated from April 2012 to March 2013 will be evaluated. Patients will be divided into 3 groups (n=53) by using computer-generated random numbers. Randomization was simple, individual using a random number table and the ratio of 1:1. In this study, Blinding was not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 20-40 years with male factor or unexplained infertility and basal FSH less than 12.

Intervention groups

Group 1 will receive 500 IU of human chorionic gonadotropin (hCG), group 2 will receive 1000 IU of hCG intrauterine injection before embryo transfer, and the control group will undergo embryo transfer (2-3 embryos) without hCG preceding intrauterine injection. Approximately 7 minutes after intrauterine HCG injection, 2-3 embryos will be transferred via another soft catheter (Cook). For luteal phase support, intramuscular injection of 100 mg progesterone will be used.

Main outcome variables

primary outcomes: Chemical and Clinical pregnancy rates, Implantation rate. secondary outcome: abortion rate

General information

Reason for update

Updating the date of sampling and the end of the clinical trial and things such as the exact mention of randomization, inclusion/exclusion criteria and study outcomes.

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091310328N3**
Registration date: **2013-01-12, 1391/10/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-09, 1401/08/18**

Update count: **2**

Registration date

2013-01-12, 1391/10/23

Registrant information

Name

Sima Janati

Name of organization / entity

Research and Clinical Center for Infertility, Dezful
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Research and Clinical Center for Infertility, Shahid sadoughi university of medical sciences, Yazd

Expected recruitment start date

2012-04-05, 1391/01/17

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

2012-04-05, 1391/01/17

Actual recruitment end date

2013-03-19, 1391/12/29

Trial completion date

2013-09-20, 1392/06/29

Scientific title

The effect of intrauterine human chorionic gonadotropin injection before embryo transfer on the implantation and pregnancy rate in infertile patients: A randomized clinical trial

Public title

The effect of intrauterine human chorionic gonadotropin injection on pregnancy outcomes in infertile patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

female age in the range of 20-40 years male factor infertility unexplained infertility basal FSH less than 12.

Exclusion criteria:

azoospermia, presence of uterine myoma endometriosis hydrosalpinges previous IVF/ICSI trials (successful or unsuccessful) history of endocrine diseases such as diabetes and thyroid dysfunction previous history of hysteroscopic operation due to submucosal myoma, and intrauterine synechia.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **159**

Actual sample size reached: **159**

Randomization (investigator's opinion)

Randomized

Randomization description

Women who met the inclusion criteria were numbered from 1 to 159 in order of referral. After being explained about the study method and obtaining informed consent two columns of 53 random numbers from 1-159 were produced using statistical soft version Minitab 14 software (Minitab. LLC, 2014. Minitab, Available at: <http://www.minitab.com>); numbers that were not in these columns were considered as third group. Each lists was randomly assigned to one of the intervention groups A, B and C (control). The simple randomization method was used. Envelopes and codes were assigned for all participants. Group one was marked with A, group two with B and group three with C. A code has been assigned to each envelope and this code was recorded for each participant.

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**

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, Yazd

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Research and Clinical Center for Infertility, Bouali Ave, Safayeh, Yazd

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Approval date

2012-03-15, 1390/12/25

Ethics committee reference number

3771

Health conditions studied**1****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**

Implantation rate

Timepoint

Identified through vaginal or abdominal ultrasound 4-5 wks after the embryo transfer.

Method of measurement

Observation of number of gestational sacs by transvaginal ultrasonography per 100 embryo transfer

2**Description**

Chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

BHCG test

3**Description**

Clinical pregnancy

Timepoint

4 -5 weeks after embryo transfer

Method of measurement

observation of fetal heart activity by trans vaginal or abdominal ultrasound

Secondary outcomes**1****Description**

Abortion

Timepoint

Before the 20th week of pregnancy

Method of measurement

Abortion product observation (placenta and fetus residual)

Intervention groups**1****Description**

In control group (n=53) in time of monitoring when at least three follicles 18 mm to be seen on ultrasound, 10,000 units HCG will be injected. 36 hours after puncturing oocytes, IVF or ICSI will be performed and 48-72 hours after 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 .

Category

Treatment - Drugs

2**Description**

In group 1 intervention (n=53) in time of monitoring when at least three follicles 18 mm to be seen on ultrasound, 10,000 units HCG will be injected. 36 hours after puncturing oocytes, IVF or ICSI will be performed. Culture media will added to a vial HCG 5000 IU and will be get HCG dilution requirement(500 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 500 IU of hCG through a soft catheter(Cook) will injected intrauterine. Approximately 7minutes after intrauterine HCG injection, between 2-3 embryo through another soft catheter(Cook) embryo transfer (ET) will be performed. For luteal phase support progesterone 100 mg intramuscular injection will used .

Category

Treatment - Drugs

3**Description**

In group 2 intervention (n=53) in time of monitoring when at least three follicles 18 mm to be seen on ultrasound, 10,000 units HCG will be injected. 36 hours after puncturing oocytes, IVF or ICSI will be performed. Culture media will added to a vial HCG 5000 IU and will be get HCG dilution requirement(1000 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 1000 IU of hCG through a soft catheter(Cook) will injected intrauterine. Approximately 7minutes after intrauterine HCG injection, between 2-3 embryo through another soft catheter(Cook) embryo transfer (ET) will be performed. For luteal phase support progesterone 100 mg intramuscular injection will used .

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Science ,Yazd

Full name of responsible person

Dr.Sima Janati

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vise Canceled of Shahid Sadoughi University of Medical Sciences of Yazd, Research and Clinical Center

Full name of responsible person

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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

Vice Canceled of Shahid Sadoughi University of Medical Sciences of Yazd, Research and Clinical Center

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**

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences Yazd

Full name of responsible person

Dr.Sima Janati

Position

Assisted Professor of Obstetrics and Gynecology, fellowship of infertility in state of training

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

Dr.Razieh Dehghani Firouzabadi

Position

Associate professor of Obstetrics and Gynecology, fellow ship of infertility

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences Yazd

Full name of responsible person

Dr. Sima Janati

Position

Assisted professor of Obstetrics and Gynecology, fellowship of infertility in state of training

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All participant data sets are to be shared

When the data will become available and for how long

2 months after the result publication

To whom data/document is available

Researchers working in academic and scientific institutes, Journal editors and Reviewers

Under which criteria data/document could be used

Submission of an official application via the agent that is legally in charge

From where data/document is obtainable

Yazd Reproductive Sciences Institute, Bouali Ave, Yazd, Iran. 983538247085

What processes are involved for a request to access data/document

Immediately after the Submission of an official application via the agent that is legally in charge (About a month) by sending an email to janati@dums.ac.ir.

Comments