

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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)

###### Phone

+98 61 4242 9781

###### 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

**Street address**

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

**City**

Yazd

**Province**

Yazd

**Postal code**

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

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yazd-rsi@ssu.ac.ir

**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**

Dr. Razieh Dehghani Firouzabadi

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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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## 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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## Person responsible for updating data

### Contact

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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

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Specialist

**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**