

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 2026

**compairig the efficacy of intramuscular injection of HCG(human chorionic gonadotropin )before embryo transfer versus intrauterine injection with control group on clinical pregnancy in infertile women canditate for ART (Assisted Reproductive Technology)cycle**

### Protocol summary

#### Summary

Objective: to evaluate effect of hcg for luteal phase support on increasing the probability of clinical pregnancy rates in ART cycles. Design: Randomized double blind clinical trial single center Setting and conduct: 300 women refered to Shariati hospital in 2014, will be divided into three groups by means of computer generated randomization program. Intervention: Patients will receive either GnRH agonist(long protocol)or GnRH antagonist protocol. For agonist group, daily injection of Buserlin 0.5 mg subcutaneous (sc) will start on the 21st day of preceding cycle. The dose will reduce to 0.25mg on commencement of menstrual bleeding. Gonadotropin stimulating hormone(rFSH or HMG) will start on the second day of menstrual bleeding to control ovarian stimulation, dose range between 150 -450 IU. Administration of drugs will continue till 3 follicles with 18 mm. Patients who receive antagonist protocol, rFSH or HMG will start on the second day and continue till the size of follicles become 14 mm, then GnRH antagonist(Cetrotide, 0.25mg, sc) will start and continue till three follicles will reach 18mm. then 10000 IU hcg (human chorionic gonadotropin )intramuscular will administer. Ovum retrieval will undertake 36 h after hcg administration, under sonographic guide with 17 guage needle. embryo transfer(ET) will perform on day 2 or 3 after ovum retrieval.on days of ET, 1500 IU hcg will inject for patients in one group and 500 IU hcg intrauterine will inject before ET in another group with control group . Main outcome measures variables: clinical pregnancy will be identified by development of a gestational sac. Secondary consequence: increased implantation rate.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2014050316912N2**

Registration date: **2014-11-23, 1393/09/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2014-11-23, 1393/09/02

#### Registrant information

##### Name

Saeedeh Gharahjeh

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8873 6218

##### Email address

s-gharahgeh@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for Research, Tehran University of Medical Sceinces

#### Expected recruitment start date

2014-08-11, 1393/05/20

#### Expected recruitment end date

2014-12-22, 1393/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

**Scientific title**

comparing the efficacy of intramuscular injection of HCG(human chorionic gonadotropin )before embryo transfer versus intrauterine injection with control group on clinical pregnancy in infertile women candidate for ART (Assisted Reproductive Technology)cycle

**Public title**

Effect of HCG (human chorionic gonadotropin) injection on clinical pregnancy in ART (Assisted Reproductive Technology) cycles

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: couples undergoing ART with their own gametes; good and high responder women; women age less than 40, FSH level less than 10 mIU/ml on third day of menses, AMH more than 1.1 ng/ml; couples having at least one embryo available for transfer. Exclusion criteria: couples undergoing ART with donation gamete; azospermia; poor responder women: women age more than 40, FSH level more than 10 mIU/ml on third day of menses, AMH less than 1.1 ng/ml and less than 4 follicles in previous ART cycle.

**Age**

From **16 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **200**

**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**

Medical ethics committee, sixth floor, university central organization, Ghods street, Keshavarz avenue

**City**

Tehran

**Postal code**

14114

**Approval date**

2014-08-10, 1393/05/19

**Ethics committee reference number**

93/130/985/ص

**Health conditions studied****1****Description of health condition studied**

infertility

**ICD-10 code**

N97.4

**ICD-10 code description**

female infertility associated with male factor

**Primary outcomes****1****Description**

clinical pregnancy

**Timepoint**

eight weeks after intervention

**Method of measurement**

vaginal sonography

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

Implantation rate

**Timepoint**

Ten weeks after intervention

**Method of measurement**

vaginal sonography

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

The day of embryo transfer, 1500 IU hcG (human chorionic gonadotropin) will be injected intermuscular in one group

**Category**

Treatment - Drugs

**2****Description**

The day of embryo transfer, 500 IU hcG (human chorionic gonadotropin) will be injected 7 minutes before embryo transfer

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Dr Shariati Hospital

**Full name of responsible person**

Saeedeh Gharahjeh

**Street address**

Infertility department, second floor, Shariati Hospital,  
Jalal al ahmad avenue

**City**

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**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for Research , Tehran University of  
Medical Sceinces

**Full name of responsible person**

Dr Akbar Fotouhi

**Street address**

Vice Chancellor for Research, Second floor, Tehran  
University of Medical Sciences, 16 Azar Avenue,  
Keshavarz Boulevard

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research , Tehran University of  
Medical Sceinces

**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 of Medical Sciences

**Full name of responsible person**

Saeedeh Gharahjeh

**Position**

Infertility Fellowship

**Other areas of specialty/work****Street address**

## Person responsible for scientific inquiries

#### Contact

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Infertility Fellowship

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Dr.gharahgeh\_1388@yahoo.com

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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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*