

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

**Evaluation the effect of intrauterine injection of recombinant human chorionic gonadotropin at different doses, before embryo transfer in improvement of implantation and pregnancy rates in in vitro fertilization/intracytoplasmic sperm injection: a prospective randomised controlled trial study.**

### Protocol summary

#### Summary

Objective: Evaluation of intrauterine injection of recombinant human chorionic gonadotropin at different doses before embryo transfer in improvement of implantation and pregnancy rates in in vitro fertilization/intracytoplasmic sperm injection Design: parallel randomised controlled trial ,single blind Setting: The Mother & Child hospital, IVF-ET Center. Participants: Infertility patients younger than 40 years who referred for IVF-ICSI at the reproductive medicine center of The Mother & Child hospital. 420 patients fulfilled the study requirements. The inclusion criteria were female age under 40 years old with infertility. Exclusion criteria were previous IVF/ICSI trials, including a successful trial, endometriosis, azoospermia, uterine myoma or previous myomectomy, or the existence of hydrosalpinges. Sample size: 420 patients Intervention(s): The study groups (n = 105 in each group) received different doses ( 500 µg ,250 ,125 of rhCG intrauterine injection 12 minutes before ET. The control group (n = 105) underwent ET without rhCG. Intervention time: intrauterine injection of rhCG 12 minutes before ET. Main Outcome Measure(s): Clinical pregnancy rate (PR) and implantation rate (IR).

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2015020921008N1**  
Registration date: **2015-04-11, 1394/01/22**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2015-04-11, 1394/01/22

#### Registrant information

##### Name

Gooya Madadi

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3227 9715

##### Email address

gmadadi@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Shiraz University of Medical Sciences

#### Expected recruitment start date

2015-01-21, 1393/11/01

#### Expected recruitment end date

2015-07-23, 1394/05/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation the effect of intrauterine injection of recombinant human chorionic gonadotropin at different doses, before embryo transfer in improvement of implantation and pregnancy rates in in vitro

fertilization/intracytoplasmic sperm injection: a prospective randomised controlled trial study.

### Public title

Evaluation of intrauterine injection of recombinant human chorionic gonadotropin at different doses in improvement of pregnancy rates in in vitro fertilization/intracytoplasmic sperm injection

### Purpose

Treatment

### Inclusion/Exclusion criteria

The inclusion criteria: female age under 40 years old with infertility. Exclusion criteria: previous IVF/ICSI trials, including a successful trial, endometriosis, azoospermia, uterine myoma or previous myomectomy, or the existence of hydrosalpinges.

### Age

From **18 years** old to **40 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **420**

### Randomization (investigator's opinion)

N/A

### 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

Medical Science Researching, Shiraz univercity of Medical Science

##### Street address

Shiraz University of Medical Science , Zand Street

##### City

Shiraz

##### Postal code

##### Approval date

2015-01-25, 1393/11/05

##### Ethics committee reference number

ct-p-9387-8237

## Health conditions studied

### 1

#### Description of health condition studied

Female Infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female Infertility

## Primary outcomes

### 1

#### Description

implantation rate

#### Timepoint

two weeks after embryo transfer

#### Method of measurement

conventional pregnancy test

## Secondary outcomes

### 1

#### Description

Clinical pregnancy rate

#### Timepoint

three weeks after a positive pregnancy test

#### Method of measurement

ultrasound

## Intervention groups

### 1

#### Description

Intervention group: receiving rhCG as intrauterine injection 12 minutes before ET. .

#### Category

Treatment - Drugs

### 2

#### Description

Control group: undergoing ET without a previous intrauterine injection of rhCG.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mother & Child hospital

##### Full name of responsible person

dr Gooya Madadi

##### Street address

Shiraz University of Medical Sciences, Zand Street,  
Shiraz

**City**  
Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Dr Basir Hashemi

**Street address**  
Shiraz University of Medical Sciences, Zand Street,  
Shiraz

**City**  
Shiraz

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Shiraz University of Medical Sciences

### 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**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
dr Gooya Madadi

**Position**  
Fellowship of Obstetrics & GYN, Infertility

### Other areas of specialty/work

**Street address**  
Shiraz university of medical science , zand street

**City**  
Shiraz

### Postal code

**Phone**  
+98 71 3227 9715

### Fax

**Email**  
gmadadi@sums.ac.irs.kharati@yahoo.com

### Web page address

## Person responsible for scientific

## inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Science

**Full name of responsible person**  
Dr afsoon zarei

**Position**  
Obstetrics and Gynecologist / infertility fellowship

### Other areas of specialty/work

**Street address**  
Shiraz University of Medical Science , Zand Street

**City**  
Shiraz

### Postal code

**Phone**  
+98 71 3227 9715

### Fax

**Email**  
zareia@sums.ac.irs.kharati@yahoo.com

### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Science

**Full name of responsible person**  
sara kharati

**Position**  
researcher

### Other areas of specialty/work

**Street address**  
Shiraz University of Medical Science , Zand Street

**City**  
Shiraz

### Postal code

**Phone**  
+98 71 3628 1591

### Fax

**Email**  
s.kharati@yahoo.com

### Web page address

## 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*