

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of intra-uterine hCG injection versus placebo in improving implantation in women fertilized with IVF method: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect intra-uterine hCG injection versus placebo in improving implantation in women fertilized with IVF method. Design: a randomized clinical trial. Setting and conduct: The eligible women fertilized with IVF method who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: age of 18 to 40 years; the cause of infertility is male sex. Exclusion criteria: using OCP or any kind of hormonal products before IVF; azoospermia; having myoma or history of myomectomy; endometriosis. Intervention group: Intra-uterine hCG injection 500 U single dose. Control group: Without injection. Primary outcome: (a) assessing pregnancy 2 weeks after intervention using pregnancy test; (b) assessing pregnancy sock 3 weeks after intervention using ultrasonography. Secondary outcome: Assessing abortion before 20 weeks of pregnancy with taking history. Randomization: Random assignment of the patients to the intervention and control groups one at a time. Blinding: Not blinded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510079014N81**

Registration date: **2015-10-20, 1394/07/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-20, 1394/07/28

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intra-uterine hCG injection versus placebo in improving implantation in women fertilized with IVF method: a randomized clinical trial

Public title

Effect of intra-uterine hCG injection versus placebo in improving implantation in women fertilized with IVF method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 18 to 40 years; the cause of infertility is male sex. Exclusion criteria: using OCP or any kind of hormonal products before IVF; azoospermia; having myoma or history of myomectomy; endometriosis.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-05-26, 1394/03/05

Ethics committee reference number

IR.UMSHA.REC.1394.70

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

assessing pregnancy

Timepoint

2 weeks after intervention

Method of measurement

using pregnancy test

2

Description

assessing pregnancy sock

Timepoint

3 weeks after intervention

Method of measurement

using ultrasonography

Secondary outcomes

1

Description

Assessing abortion

Timepoint

before 20 weeks of pregnancy

Method of measurement

with taking history

Intervention groups

1

Description

Intra-uterine hCG injection 500 U single dose

Category

Treatment - Drugs

2

Description

Without injection

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Sima Saffary

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan
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**

Fatemieh Hospital

Full name of responsible person

Dr Sima Saffary

Position

Resident of Gynecology

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

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code**Phone**

+98 81 3828 3939

Fax**Email**

simasaffary@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Fatemieh Hospital

Full name of responsible person

Dr Soghra Rabiee

Position

Gynecologist

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

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code**Phone**

+98 81 3828 3939

Fax**Email**

rebieeso@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

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

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.ac.ir

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