# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 May 2026

## Evaluation of human chorionic gonadotropin (HCG) addition during secretary phase in frozen-thawed embryo transfer cycles

### Protocol summary

**Study aim**
The aim of our study is to assess the advantage of HCG injection in secretory phase plus estrogen and progesterone to transfer cryopreserved-thawed embryos

**Design**
Primary outcome chemical pregnancy that is evaluated 2 weeks after embryo transfer.

**Settings and conduct**
This randomized clinical trial was conducted at the Yazd Research and Clinical Center for Infertility.This study was a randomized clinical trial. Infertile women who were candidates for frozen-thawed embryo transfers entered the study and were divided into two groups, HCG and control. The endometrial preparation method was similar in both groups.

**Participants/Inclusion and exclusion criteria**
All women have failed previous in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI), and they have cryopreserved embryos transfer.Women older than 38 years, those with a body mass index (BMI) >30 kg/m2, history of endocrine disorders, and severe endometriosis were excluded from the study.

**Intervention groups**
In case group, HCG is injected 5000 IU in the first day of progesterone injection and in the embryo transfer time.

**Main outcome variables**
Primary outcome includes chemical pregnancy that is evaluated 2 weeks after embryo transfer

### General information

**Reason for update**
up date clinical trial base on the latest changes in methods and enters results

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT201107266420N4**
Registration date: **2011-09-18, 1390/06/27**
Registration timing: **retrospective**
Last update: **2021-03-16, 1399/12/26**
Update count: **2**

**Registration date**
2011-09-18, 1390/06/27

**Registrant information**

**Name**
Maryam Eftekhar

**Name of organization / entity**
Yazd Research and Clinical Center for Infertility

**Country**
Iran (Islamic Republic of)

**Phone**
+98 35182470856

**Email address**
eftekhar@ssu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**
Shahid sadoughi university of medical sciences

**Expected recruitment start date**
2009-01-01, 1387/10/12

**Expected recruitment end date**
2010-12-30, 1389/10/09

**Actual recruitment start date**
2009-01-01, 1387/10/12

**Actual recruitment end date**
2010-12-30, 1389/10/09

**Trial completion date**
2011-06-30, 1390/04/09

**Scientific title**
Evaluation of human chorionic gonadotropin (HCG) addition during secretary phase in frozen-thawed embryo transfer cycles

**Public title**
Comparison of two protocols for transfer of the frozen embryos

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Inclusion criteria: History of in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) fail; cryopreservation of excess embryos

**Exclusion criteria:**

age >38 years; BMI>30; history of endocrine disorder; severe endometriosis.

**Age**

From **18 years** old to **38 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

Actual sample size reached: **130**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

randomization by table of random numbers

**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**

Yazd reserch and clinical center for infertility

**Street address**

Booali street

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Approval date**

2011-06-20, 1390/03/30

**Ethics committee reference number**

928

## Health conditions studied

### 1

**Description of health condition studied**

infertility

**ICD-10 code**

N99

**ICD-10 code description**

Postprocedural disorders of genitourinary system, not elsewhere classified

## Primary outcomes

### 1

**Description**

chemical pregnancy

**Timepoint**

2 weeks

**Method of measurement**

serum BHCG

## Secondary outcomes

### 1

**Description**

clinical sonography

**Timepoint**

2 weeks

**Method of measurement**

sonography

## Intervention groups

### 1

**Description**

Intervention: all women receive estradiol valerate 6 mg PO per day from the second day of menstrual cycle. Endometrial thickness is assessing by using vaginal ultrasonography since 13th day of cycle. Progesterone 100mg is injected when endomethrial thickness reaches to 8 mm. Estradiol and progesterone consumption are continued until 10th weeks of gestational age. HCG 5000 IU is injected in the first day of progesterone injection and in the day of embryo transfer.

**Category**

Treatment - Drugs

### 2

**Description**

Control: all women receive estradiol valerate 6 mg PO per day from the second day of menstrual cycle. Endometrial thickness is assessing by using vaginal ultrasonography since 13th day of cycle. Progesterone 100mg is injected when endomethrial thickness reaches to 8 mm. Estradiol and progesterone consumption are continued until 10th weeks of gestational age.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Yazd reserch and clinical center for infertility
**Full name of responsible person**
Maryam Eftekhar
**Street address**
Bouali Avenue, Safayeh
**City**
Yazd
**Province**
Yazd
**Postal code**
8916877391
**Phone**
+98 35 3824 7085
**Fax**
**Email**
eftekhar@ssu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Yazd reaserch and clinical center for infertility
**Full name of responsible person**
Dr.Abbas Aflatoonian
**Street address**
Bouali Avenue, Safayeh
**City**
Yazd
**Province**
Yazd
**Postal code**
8916877391
**Phone**
+98 35 3824 7085
**Email**
abbas_aflatoonian@yahoo.com

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Yazd reaserch and clinical center for infertility
**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**
Yazd research center for infertility
**Full name of responsible person**
Dr Maryam Eftekhar
**Position**
Assisted professor
**Latest degree**
Medical doctor
**Other areas of specialty/work**
**Street address**
Bouali Avenue, Safayeh
**City**
Yazd
**Province**
Yazd
**Postal code**
8916877391
**Phone**
+98 35 1824 7085
**Fax**
**Email**
eftekhar@ssu.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Yazd reserarch and clinical center for infertility
**Full name of responsible person**
Dr Maryam Eftekhar
**Position**
Assisted professor
**Latest degree**
Medical doctor
**Other areas of specialty/work**
**Street address**
Bouali Avenue, Safayeh
**City**
Yazd
**Province**
Yazd
**Postal code**
8916877391
**Phone**
+98 35 1824 7085
**Fax**
**Email**
eftekhar@ssu.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Yazd research and clinical center for infertility
**Full name of responsible person**
Dr Maryam Eftekhar

**Position**
Assisted professor
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
Bouali Avenue, Safayeh
**City**
Yazd
**Province**
Yazd
**Postal code**
8916877391
**Phone**
+98 35 1824 7085
**Fax**
**Email**
eftekhar@ssu.ac.ir
**Web page address**

## 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**
A journal in which the results are published
**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**
Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its referral to the security and after completion of the relevant forms, the request is referred to the research experts and then get the data.
**Comments**

## Trial results

**Please tick if results have been published**
Yes
**Summary result posting date**
2021-03-08, 1399/12/18
**Table of baseline comparison**

Basic patient characteristics in the two groups

| Variables | HCG group Mean (SD) | Control group Mean (SD) | P value |
|---|---|---|---|
| **Age (Years)** | 28.47 ± 4.14 | 28.84 ± 3.71 | 0.549 |
| **Duration of infertility (Years)** | 6.58 ± 2.9 | 6.09 ± 2.74 | 0.368 |
| **Basal FSH (IU/L)** | 5.15 ± 1.66 | 5.60 ± 1.72 | 0.135 |
| **BMI (kg/m$^2$)** | 23.67 ± 2.43 | 23.86 ± 2.3 | 0.661 |
| **Etiology of infertility** | | | |
| **Ovulatory , n (%)** | 13 (20) | 13 (20) | 0.201 |
| **Tubal, n (%)** | 9 (13.8) | 10 (15.4) | |
| **Unexplained, n (%)** | 0 (0.0) | 4 (3.1) | |
| **Mixed, n (%)** | 42 (64.6) | 35 (53.8) | |
| **Male, n (%)** | 1 (1.5) | 4 (3.1) | |
| **Total, n (%)** | 63 (100) | 65 (100) | |

**Participant flow diagram**
**Table of variable outcomes' results**

ART outcome in both groups

| Variables | HCG group | Control group | P Value |
|---|---|---|---|
| **Implantation rate (%)** | 21.02 | 17.44 | 0.488 |
| **Chemical pregnancy rate, n (%)** | 27 (41.5) | 25 (38.5) | 0.429 |
| **Clinical pregnancy rate, n (%)** | 22 (30.8) | 20 (30.8.7) | 0.426 |
| **Ongoing pregnancy rate, n (%)** | 20 (30.8) | 18 (27.7) | 0.424 |
| **Miscarriage rate, n (%)** | 7 (25.9) | 7 (28.0.4) | 0.556 |
| **Endometrial thickness (mm)** | 8.83±1.6 | 9.08±1.2 | 0.528 |

**Table of adverse events**

**First publication date**

2012-12-30, 1391/10/10

**Abstract of published paper**

Abstract Background: Human chorionic gonadotropin (HCG), one of the initial embryonic signals, is probably a major regulator of the embryo-endometrial relationship. This study aims to assess the advantage of HCG supplementation during the secretory phase of hormonally prepared cycles for the transfer of cryopreserved-thawed embryos. Materials and Methods: This study was a randomized clinical trial. Infertile women who were candidates for frozen-thawed embryo transfers entered the study and were divided into two groups, HCG and control. The endometrial preparation method was similar in both groups: all women received estradiol valerate (6 mg) po per day from the second day of the menstrual cycle and progesterone in oil (100 mg) intramuscular (I.M.) when the endometrial thickness reached 8 mm. Estradiol and progesterone were continued until the tenth week of gestation. In the HCG group, patients received an HCG 5000 IU injection on the first day of progesterone administration and the day of embryo transfer. Results: In this study, 130 couples participated: 65 in the HCG group and 65 in the control group. There was no statistically significant difference between groups regarding basic characteristics. Implantation rate, chemical pregnancy, clinical pregnancy, ongoing pregnancy, and abortion rates were similar in both groups. Conclusion: Although HCG has some advantages in assisted reproductive technology (ART) cycles, our study did not show any benefit of HCG supplementation during the secretory phase of frozen cycles (Registration Number: IRCT201107266420N4). Keywords: ART, Implantation, Frozen Embryo, HCG