

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of human chorionic gonadotropin (HCG) addition during secretory 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 Eftekhari

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35182470856

Email address

eftekhari@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 secretory 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 research and clinical center for infertility

Full name of responsible person

Maryam Eftekhari

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Bouali Avenue, Safayeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd research and clinical center for infertility

Full name of responsible person

Dr. Abbas Afshar

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Email

abbas_afshar@yahoo.com

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

Yes

Title of funding source

Yazd research 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 Eftekhari

Position

Assisted professor

Latest degree

Medical doctor

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd research and clinical center for infertility

Full name of responsible person

Dr Maryam Eftekhari

Position

Assisted professor

Latest degree

Medical doctor

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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Web page address**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**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

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