

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Effect of adding human chorionic gonadotropin to frozen thawed embryo transfer cycles in women with history of thin endometrium: A clinical trial

#### Protocol summary

##### Summary

Objective: We design this study in order to assess adding human chorionic gonadotropin (HCG) to the conventional protocol in endometrial preparation in women with thin endometrium and a history of in vitro fertilization-embryo transfer (IVF-ET) failure. Design: 28 infertile women with thin endometrium are studied in this non-randomized clinical trial study (quasi experimental design) from September 2013 to January 2014. Inclusion and Exclusion criteria: Infertile women who are candidate for frozen-thawed (ET) with at least 2 previous failed IVF cycle, thin endometrium (thickness less than 7 mm) despite conventional treatment in previous IVF cycles (vaginal estrogen, sildenafil, vitamin E, ...). Patients with intrauterine lesion such as sub mucosal leiomyoma, history of endometriosis, and thyroid disorders are excluded. Intervention: All the patients receive 8 mg estradiol valerate from the second day of menstrual cycle and continued at least for seven days. HCG (Pregnyl®, Darou Pakhsh, Iran) are administered (150 IU, IM) from the 8th day of cycle. On the 12-13th day Trans-vaginal sonography are done and endometrial thickness are measured. If it are proper, (at least 7mm) HCG stop and after 24 h progesterone 100 mg intramuscular are injected for 3 days. Finally, ET are performed. Main outcome measures: The pregnancy test (serum  $\beta$ HCG) was done two weeks after ET. Fetal heartbeat (clinical pregnancy) was checked after 2-3 weeks after positive  $\beta$ HCG test .

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT201512082604N2**

Registration date: **2016-01-14, 1394/10/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-01-14, 1394/10/24

##### Registrant information

###### Name

Robab Davar

###### Name of organization / entity

Yazd Research and Clinical Center for Infertility

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 1824 7085

###### Email address

davar@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

##### Expected recruitment start date

2013-09-01, 1392/06/10

##### Expected recruitment end date

2015-01-01, 1393/10/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of adding human chorionic gonadotropin to frozen thawed embryo transfer cycles in women with history of thin endometrium: A clinical trial

##### Public title

Effect of adding human chorionic gonadotropin to frozen thawed embryo transfer cycles with history of thin

endometrium

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Infertile women who are candidate for frozen-thawed (ET); with at least 2 previous failed IVF cycle, thin endometrium (thickness less than 7 mm) despite conventional treatment in previous IVF cycles (vaginal estrogen; sildenafil; vitamin E; ...). Exclusion criteria: Oocyte donation; Endometriosis; Polycystic Ovary Syndrome; Intrauterine lesion such as submucosal leiomyoma; history of endometriosis; and thyroid disorders.

## Age

From **20 years** old to **40 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **25**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Research and Clinical Center for Infertility, Shahid Sadoughi University of Med

##### Street address

Research and Clinical Center for Infertility, Bouali Ave, Safaeyeh, Yazd, Iran.

##### City

Yazd

##### Postal code

8916877391

#### Approval date

2014-06-23, 1393/04/02

#### Ethics committee reference number

317

## Health conditions studied

### 1

#### Description of health condition studied

Female infertility

#### ICD-10 code

N97.2

#### ICD-10 code description

Female infertility of uterine origin

## Primary outcomes

### 1

#### Description

Clinical pregnancy

#### Timepoint

2-3 weeks after positive pregnancy test

#### Method of measurement

Fetal heartbeat after 2-3 weeks.

### 2

#### Description

Chemical pregnancy

#### Timepoint

2 weeks after embryo transfer

#### Method of measurement

serum  $\beta$ HCG

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: All the patients receive 8 mg estradiol valerate from the second day of menstrual cycle and continued at least for seven days. HCG (Pregnyl®, Darou Paksh, Iran) are administered (150 IU, IM) from the 8th day of cycle. On the 12-13th day Trans-vaginal sonography are done and endometrial thickness are measured. If it are proper, (at least 7mm) HCG stop and after 24 h progesterone 100 mg intramuscular are injected for 3 days. Finally, ET are performed

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yazd Research and Clinical Center for Infertility

##### Full name of responsible person

Robab Davar

**Street address**

Research and Clinical Center for Infertility, Bouali Ave., Safaeyeh, Yazd, Iran.

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Yazd

**Fax****Email**

r\_davar@yahoo

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

**Full name of responsible person**

Dr. Robab Davar

**Street address**

Research and Clinical Center for Infertility, Bouali Ave, Safaeyeh, Yazd, Iran.

**City**

yazd

**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, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

**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**

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, Bouali Av

**Full name of responsible person**

Dr. Robab Davar

**Position**

Gynecologist/Infertility Fellowship (M.D.)/ Associated Professor of Shahid Sadoughi University of me

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

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**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*