

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Correlation between beta Human chorionic gonadotropin ( $\beta$ -Hcg) on day 14 after embryo transfer and pregnancy outcome in IVF cycles

#### Protocol summary

##### Study aim

Correlation between beta Human chorionic gonadotropin ( $\beta$ -Hcg) on day 14 after embryo transfer and pregnancy outcome in IVF cycles. This study was designed to evaluate the relationship between human placental beta gonadotropin on day 14 after embryo transfer and pregnancy outcome in IVF cycles.

##### Design

In this prospective cross-sectional study, 177 infertile women referred to Yas Hospital for embryo transfer. All participants entered the study after performing the necessary interventions and in case of the results of the beta hCG test above 25, and all the information of the questionnaire was completed during the performed ultrasounds.

##### Settings and conduct

In this study, 177 infertile women who are candidates for fresh or frozen transfer in Yas Hospital have been selected by convenience sampling. After the necessary interventions, participants are examined for clinical pregnancy certainty and all information is recorded in a questionnaire.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: body mass index below 30; Age 20 to 42 years; Above 25 Beta HCG number on day 14  
Inclusion criteria: the presence of any uterine anomaly; Existence of chronic diseases (such as cardiovascular); Use of group D and X drugs during pregnancy

##### Intervention groups

All participants received 6 mg of estradiol daily on the second or third day of their menstrual cycle. Once the endometrium has reached a thickness of 8 mm, a 50 mg progesterone ampoule is given twice daily for three days until embryo transfer.

##### Main outcome variables

Estradiol levels; Endometrial thickness; Biochemical pregnancy; Number of embryos transferred; Number of pregnancy sacs; Implantation rate; Clinical pregnancy.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120104008611N13**

Registration date: **2022-04-05, 1401/01/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-05, 1401/01/16**

Update count: **0**

##### Registration date

2022-04-05, 1401/01/16

##### Registrant information

##### Name

Hamideh Pakniat

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 282242452

##### Email address

hpakniat@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-16, 1400/12/25

##### Expected recruitment end date

2022-10-23, 1401/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Correlation between beta Human chorionic gonadotropin ( $\beta$ -Hcg) on day 14 after embryo transfer and pregnancy outcome in IVF cycles

## Public title

Relationship between beta gonadotropin and pregnancy outcome in the in vitro fertilization cycle

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Body mass index below 30 Age between 20 to 42 years  
Have at least 3 grade A or B embryos All ladies with fresh or frozen transitions Above 25 Beta Hatch CG number on day 14

### Exclusion criteria:

Uterine anomaly Submucosal myoma Endometrial polyps  
Existence of chronic diseases (such as cardiovascular)  
Use of group D and X drugs during pregnancy

## Age

From **20 years** old to **42 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **177**

## 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 the Faculty of Medical Sciences and Health Services, University of Tehran

##### Street address

Tehran University of Medical Sciences, Central Building, Ghods Ave., Keshavarz Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

## Approval date

2021-10-31, 1400/08/09

## Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.853

## 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

Assess endometrial thickness

#### Timepoint

The second or third day of the menstrual cycle

#### Method of measurement

Using an ultrasound machine

### 2

#### Description

The estradiol level

#### Timepoint

At the beginning of the study until the endometrial thickness reaches 8 mm

#### Method of measurement

Blood sample

## Secondary outcomes

### 1

#### Description

Biochemical pregnancy

#### Timepoint

Once, 14 days after fetus transfer

#### Method of measurement

Blood sampling

### 2

#### Description

Clinical pregnancy

#### Timepoint

Once, 6 to 8 weeks after embryo transfer

#### Method of measurement

Observation of pregnancy sac and heart rate on ultrasound

## Intervention groups

## 1

### Description

Intervention group: Receiving estradiol 6 mg daily on the second or third day of the menstrual cycle, then after reaching a thickness of 8 mm endometrium, receiving 50 mg progesterone ampoule twice a day for three days until embryo transfer

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Yas hospital

#### Full name of responsible person

Hamideh Pakniat

#### Street address

Yas hospital, Next to the sarv street, North Nejatollahi street, karim khan ave

#### City

Tehran

#### Province

Tehran

#### Postal code

1597856511

#### Phone

+98 21 8608 9089

#### Email

hpakniat@qums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Sahraiyani

#### Street address

Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1416634793

#### Phone

+98 21 8163 3689

#### Email

vcr@tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran University of Medical Sciences

#### 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

Qazvin University of Medical Sciences

#### Full name of responsible person

Hamideh Pakniat

#### Position

Associate Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Kosar Hospital, Taleghani St., Qazvin

#### City

Qazvin

#### Province

Qazvin

#### Postal code

13176- 34156

#### Phone

+98 28 3323 6374

#### Email

hpakniat@qums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Hamideh Pakniat

#### Position

Kosar Hospital, Taleghani St., Qazvin

#### Latest degree

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Qazvin University of Medical Sciences

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**Email**

hpakniat@qums.ac.ir

## 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

No - There is not 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

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

The collected information is in the form of a questionnaire and is statistically analyzed.

### When the data will become available and for how long

The start of the access period is one year after the results are published

### To whom data/document is available

For obstetricians and researchers working in academic institutions

### Under which criteria data/document could be used

Evaluate the path and process of study and analyze it

### From where data/document is obtainable

For information, refer to Dr. Hamideh Pakniat. The communication channels are as follows: By sending an email to the address: hpakniat@qums.ac.ir or refer and contact Kosar Hospital at the address: Taleghani St, Qazvin. Phone: 028-33236374 Postal address: 34156-13176

### What processes are involved for a request to access data/document

After sending the e-mail, the requested information will be reviewed by the facilitator and the person responsible for the scientific response of the study. At your discretion, the requested information will be sent within 10 days after receiving the email.

### Comments