

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of pregnancy rate for the best method for endometrial preparation in natural and hormonal cycles for the transfer of freeze-thawed embryos in infertile patients

#### Protocol summary

##### Summary

The purpose of this study is to compare the clinical pregnancy rates of Natural and Hormonal cycle in frozen embryo transfer. The study will be clinical trial, randomization, single center and double blind. 200 patients of Akbar Abadi hospital infertility unit who are planning an FET cycle, will join this study. Inclusion criteria will be regular ovulatory cycles; the ages will be between 19 to 45; causes of infertility will be male factor, endometriosis, tubal factor and idiopathic; basal serum levels of FSH will be less than or equal to 10 IU/l with normal Prolactin and absence of uterine anomalies. Patients with oocyte donation will be excluded from this survey. All patients who meet the inclusion criteria will be included after being informed of study condition and filling the inform consent form; then will be divided in two groups randomly. The first group will be those with Natural cycle and second group will be Hormonal cycle. Natural cycles with 100 infertile patients will be studied based on the daily serum LH of the 10th cycle day. When the serum LH level will be decreasing, ovulation will occur 36 to 40 hours later. The embryo transfer will be scheduled 3 to 5 days after ovulation. In hormonal cycles, 4 to 6 mg of Estradiol Valerate tablet will be taken from day 3 of the cycle. This group on 12th cycle day will undergo transvaginal sonography (TVS) for evaluation of endometrial thickness and if at least endometrial thickness 8 mm observed and embryos 3 to 5 days later will be transferred. The same day SUPP Progesterone 400 mg (Cyclogest) twice daily will be started. The embryo transfer will be scheduled 3 to 5 days after starting progesterone. Primary outcome is chemical pregnancy rate that will be measured by Beta-HCG testing for 14 days after the embryo transfer. Other outcomes will be clinical pregnancy and endometrial thickness.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017081335670N1**  
Registration date: **2017-10-08, 1396/07/16**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-08, 1396/07/16

##### Registrant information

##### Name

Fatemeh Ashtari

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 86701

##### Email address

javedanimasroor.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2016-03-19, 1394/12/29

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of pregnancy rate for the best method for endometrial preparation in natural and hormonal cycles for the transfer of freeze-thawed embryos in infertile patients

**Public title**

Comparing the rate of pregnancy of Natural cycle and Hormonal cycle in frozen embryo transfer

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: regular cycle; causes of infertility are male factor; endometriosis; tubal factor; idiopathic; serum levels of FSH is less than or equal to 10 IU/l; normal Prolactin; no allergy to Estradiol and Progesterone; the absence of uterine anomalies  
Exclusion criteria: patients with oocyte donation will be excluded from this plan

**Age**

From **19 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomization is based on close envelope method

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Hemmat Highway, Tehran

**City**

Tehran

**Postal code**

۱۴۹۹۶۱۴۵۳۵

**Approval date**

2010-08-20, 1389/05/29

**Ethics committee reference number**

IR.IUMS.REC 1395.9211290001

**Health conditions studied****1****Description of health condition studied**

Infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

**Primary outcomes****1****Description**

Chemical pregnancy rate

**Timepoint**

14 days after embryo transfer

**Method of measurement**

Beta-HCG using lab kit

**Secondary outcomes****1****Description**

clinical pregnancy rate

**Timepoint**

7 weeks after embryo transfer

**Method of measurement**

fetal heart rate in ultra sonography

**2****Description**

Endometrial thickness

**Timepoint**

From the 12th day of the cycle, one day in between

**Method of measurement**

Measurement with transvaginal ultrasound

**Intervention groups****1****Description**

Control group: Natural cycles with 100 infertile patients will be studied based on the daily serum LH of the 10th cycle day. When the serum LH level will be decreasing, ovulation will occur 36 to 40 hours later. The embryo transfer will be scheduled 3 to 5 days after ovulation

**Category**

Other

## 2

### Description

Intervention group: In hormonal cycles, 4 to 6 mg of Estradiol Valerate tablet will be taken from day 3 of the cycle. This group on 12th cycle day will undergo transvaginal sonography (TVS) for evaluation of endometrial thickness and if at least endometrial thickness 8 mm observed and embryos 3 to 5 days later will be transferred.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Akbar Abadi hospital

##### Full name of responsible person

Fatemeh Ashtari

##### Street address

Shahid Akbar Abadi hospital, Molavi st, Tehran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Iran University of Medical Sciences

##### Full name of responsible person

Dr Seyed Kazem Malakouti

##### Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway, Tehran

##### City

Tehran

#### 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 of Iran 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

Iran University of Medical Sciences

#### Full name of responsible person

Fatemeh Ashtari

#### Position

Resident of Obstetrics and Gynecology

#### Other areas of specialty/work

#### Street address

Shahid Akbar Abadi hospital, Molavi st, Tehran

#### City

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+98 21 5560 6034

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el\_ashtari@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Dr Mojgan Javedani Masroor Tanha

#### Position

Assistant professor, Infertility Fellowship

#### Other areas of specialty/work

#### Street address

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#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Fatemeh Ashtari

#### Position

Resident of Obstetrics and Gynecology

#### Other areas of specialty/work

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**Fax**  
**Email**  
el\_ashtari@yahoo.com  
**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*