

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the rate of pregnancy of Natural versus modified -natural cycle for endometrial preparation in frozen embryo transfer

#### Protocol summary

##### Study aim

Comparing the rate of pregnancy of Natural versus modified -natural cycle in frozen embryo transfer

##### Design

Single blinded randomized controlled clinical trial

##### Settings and conduct

Settings: Arash Women's Hospital Blinding: Single-blind (outcome assessor and data analyst)

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: maximum age 38 years, regular menstrual cycles Exclusion criteria: PCO, endometriosis, FSH  $\geq$  12 IVF and Severe Male Factor

##### Intervention groups

Group1: will receive vaginal progesterone after positive urinary LH kit. Group 2: 5000 IU HCG injection IM state, after presenting endometrial thickness > 7 mm and 17 mm dominant follicle in transvaginal sonography.

##### Main outcome variables

Chemical pregnancy rate, clinical pregnancy rate, abortion rate, implantation rate, ongoing pregnancy rate

#### General information

##### Reason for update

Correcting Outcome Variables and blindness

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201607311556N92**

Registration date: **2016-08-24, 1395/06/03**

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

Last update: **2021-12-01, 1400/09/10**

Update count: **1**

##### Registration date

2016-08-24, 1395/06/03

##### Registrant information

Name

Shahin Akhondzadeh

##### Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5541 2222

##### Email address

s.akhond@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

2016-08-22, 1395/06/01

##### Actual recruitment end date

2018-04-20, 1397/01/31

##### Trial completion date

2018-08-22, 1397/05/31

##### Scientific title

Comparing the rate of pregnancy of Natural versus modified -natural cycle for endometrial preparation in frozen embryo transfer

##### Public title

Comparing the rate of pregnancy of Natural versus modified -natural cycle in frozen embryo transfer

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Age below 38 Regular menstrual cycle Normal BMI The previous history of up to two IVF cycle

###### Exclusion criteria:

PCOD History of endometriosis ( grade  $\geq 3$ ) according to AFS Abnormal uterin FSH  $\geq 12$  Sever male factor

#### Age

To **38 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **140**

Actual sample size reached: **110**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The patients underwent FET according to a computer-generated concealed randomization list using the block randomization method. There were six blocks. The statistician prepared random treatment assignments in sealed envelopes to conceal the randomization list from all research staff involved in enrollment and assessment.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

This study was designed as a single blinded study and the outcome investigators (infertility clinic's midwife and the gynecologist who performed ultrasound assessments), and the statistician were unaware of the type of intervention until the end of the study.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

###### Street address

Qods St, Keshavarz Blvd, Tehran, Iran

###### City

Tehran

###### Province

Tehran

###### Postal code

1417653761

##### Approval date

2016-08-09, 1395/05/19

##### Ethics committee reference number

IR.TUMS.MEDICINE.RBC.1395.426

### Health conditions studied

#### 1

##### Description of health condition studied

In vitro fertilization

##### ICD-10 code

Z31.2

##### ICD-10 code description

In vitro fertilization

### Primary outcomes

#### 1

##### Description

Clinical pregnancy rate

##### Timepoint

6 weeks of pregnancy

##### Method of measurement

Ultrasonography

#### 2

##### Description

Abortion rate

##### Timepoint

During 20 weeks of pregnancy

##### Method of measurement

Ulthrasonography, B-HCG

#### 3

##### Description

Chemical Pregnancy Rate

##### Timepoint

2 weeks after embryo transfer

##### Method of measurement

Blood Pregnancy Test (BHCG)

### Secondary outcomes

#### 1

##### Description

Implantation

##### Timepoint

Gestational sac in 5 weeks of pregnancy

##### Method of measurement

ultrasonography

#### 2

##### Description

Ongoing Pregnancy Rate

##### Timepoint

12 weeks of gestation

##### Method of measurement

The rate of pregnancies that continued  $\geq 12$  weeks of gestation.

### 3

#### **Description**

Endometrial thickness

#### **Timepoint**

At regular intervals until the endometrial thickness reaches above 7 mm

#### **Method of measurement**

Transvaginal Ultrasound

### 4

#### **Description**

No. of embryos transferred

#### **Timepoint**

At the time of embryo transfer

#### **Method of measurement**

Embryologist's report

## **Intervention groups**

### 1

#### **Description**

The control group(1): progesteron pessary administration after positive urinary LH kit

#### **Category**

Treatment - Drugs

### 2

#### **Description**

5000 Iu HCG injection IM state, after presenting endometrial thickness>7 mm and 17 mm dominant follicule in trans-vaginal ultrasonography

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Arash women's hospital

##### **Full name of responsible person**

Dr Ladan Kashani

##### **Street address**

Arash women's hospital, Reslat highway, Tehranpars, Rashid Ave.

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1653915981

##### **Phone**

+98 21 7788 3283

##### **Email**

kashani\_ladan@tums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical sciences/Vice chancellor for research

##### **Full name of responsible person**

Dr Akbar Fotoohi

##### **Street address**

Vice chancellor for research, Tehran University of Medical sciences

##### **City**

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##### **Email**

resdeputy@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/Vice chancellor for research

#### **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**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Saedeh Aref

##### **Position**

Resident

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

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Tehran University of Medical Sciences  
**Full name of responsible person**  
Ladan Kashani  
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Assistant professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences

**Full name of responsible person**  
Maryam Farid Mojtahedi  
**Position**  
assistant professor  
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Subspecialist  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available