

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### A Comparative evaluation of the effect of Estradiol jell and Valerate Estradiol tablet in preparing endometrium for frozen embryo transfer cycle without agonist suppression.

#### Protocol summary

##### Summary

For the purpose of the endometrial preparing, there are different regimes including using different products of estrogen and progesterone. Estrogen is available as a composite of valerate estradiol tablet, dermal jell, dermal and vaginal patch. Taking the side effects of oral esteroid on lipoprotein and the coagulation factors, it is useful to use estrogen jell. As a result, taking the side effects of oral esteroid into account, it is important to use products with less side effects such as jell. A study was conducted in 2016-2017 on 100 infertile women who were under treatment with the acceptance conditions (between 20-45 years old, and are candidate to frozen embryo transfer). The participants took part in the study for 6 months in Vali-asr Clinic for Infertility, and without agonist suppression they were randomly in single blind divided into two groups. In the two groups, the first day of menstrual cycle the amount of estradiol was checked. In the first group from the first day of menstrual cycle 6 mg of estradiol was daily given. After one week, ultrasound was done, and by the start of the triple-line endometrium estradiol was checked. In the second group, from the first day of menstrual cycle 4.5 mg of estradiol jell equaling three line of the ruler and 4 mg of oral estradiol in the upper arm or thigh area was used. The two groups were compared according to estradiol serum amount, size of endometrium thickness (primary outcome) and clinical pregnancy rate (secondary outcome).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201701083950N5**

Registration date: **2017-03-13, 1395/12/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-03-13, 1395/12/23

##### Registrant information

###### Name

Mina Jafarabadei

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6658 1616

###### Email address

jafarabadi@tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2016-04-03, 1395/01/15

##### Expected recruitment end date

2017-02-03, 1395/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A Comparative evaluation of the effect of Estradiol jell and Valerate Estradiol tablet in preparing endometrium for frozen embryo transfer cycle without agonist suppression.

##### Public title

A Comparative evaluation of the effect of Estradiol jell and Valerate Estradiol tablet in preparing endometrium .

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: patients candidate for freeze embryo transfer; age 20-45 years old. Exclusion criteria: patients candidate for fresh embryo transfer; ovarian failure; reduced response to ovarian stimulation and oocyte recipient candidates; patients with hyperstimulation ( ovaries hyperstimulation ) that have not done embryo transfer in fresh cycles; fetus with bad quality.

### **Age**

From **20 years** old to **45 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **100**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

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**

Tehran University of Medical Sciences, Ghods Street, Keshavarz blvd.

##### **City**

Tehran

##### **Postal code**

14194

#### **Approval date**

2016-12-21, 1395/10/01

#### **Ethics committee reference number**

IR.TUMS.IKHC.REC.1395.1955

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Female infertility associated with anovulation

#### **ICD-10 code**

N97.0

#### **ICD-10 code description**

Female infertility, unspecified

## **Primary outcomes**

### 1

#### **Description**

Endometrial thickness

#### **Timepoint**

One week after treatment

#### **Method of measurement**

Vaginal sonography

### 2

#### **Description**

Estradiol quantity

#### **Timepoint**

One week after treatment

#### **Method of measurement**

Lab Test

## **Secondary outcomes**

### 1

#### **Description**

Clinical Pregnancy

#### **Timepoint**

Three weeks after do positive of pregnancy taset

#### **Method of measurement**

Transvaginal sonography

### 2

#### **Description**

Chemical pregnancy

#### **Timepoint**

14 days after embryo transfer

#### **Method of measurement**

B-HCG Test

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: the first day of menstrual cycle the amount of estradiol was checked. From the first day of menstrual cycle 6 mg of estradiol was daily given. After one week, ultra-sound was done, and by the start of the triple-line endometrium estradiol was checked. If endometrial thickness greater than 8 mm and estradiol is greater than 200 pictogram, embryo transfer is done. Intramuscular progesterone prescribe once a day

(100mg) 4 days before the ET and will continue for up to 12 weeks of pregnancy.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group 2: from the first day of menstrual cycle 4.5 mg of estradiol jell equaling three line of the ruler and 4 mg of oral estradiol in the upper arm or thigh area was used. After one week, ultra-sound was done, and by the start of the triple-line endometrium estradiol was checked. If endometrial thickness greater than 8 mm and estradiol is greater than 200 pictogram, embryo transfer is done. Intramuscular progesterone prescribe once a day (100mg) 4 days before the ET and will continue for up to 12 weeks of pregnancy.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Vali Asr Infertility Clinic

**Full name of responsible person**

Dr. Amal Shoman

**Street address**

Valiasr Infertility Clinic, Imam Khomeini Hospital, Keshavarz Blvd.

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Younesian

**Street address**

Deputy of research and technolog , Floor N.6, Central Bulding , Ghods Street.

**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, Tehran 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**

Reproductive Health Research Center

**Full name of responsible person**

Amal Shoman

**Position**

Infertility Flowship

**Other areas of specialty/work**

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**Position**

Associate Professor

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## Person responsible for updating data

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Fedyeh Haghollahi

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## 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*