

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of effect of transdermal estradiol and estradiol valerate on endometrial receptivity in frozen-thawed embryo transfer cycles

#### Protocol summary

##### Summary

The aim of this prospective randomized study ,is to compare the two methods of endometrial preparation with oral estradiol and 17 $\beta$ -estradiol transdermal patch. Total number of 90 patients that nominated of frozen - thawed embryo transfer will referred to Yazd Research and Clinical Center of Infertility from April 2012 through March 2013 . Inclusion criteria: female Exclusion criteria: age under 20 and more than 40 years; polycystic ovarian syndrome ; endocrine or metabolic disorder;endometriosis ; egg donor . patients by random table will be divide in two groups. In control group , for endometrial preparation will started from 2nd day of cycle oral estradiol 6 mgr daily and in study group ,at the same time of menses will applied 17-B estradiol transdermal patches 100 microgram every other day that each patch will removed after four days. In both group clinical monitoring by transvaginal ultrasound will done on 11th day of menstruation to measure endometrial thickness. While endometrial thickness is less than 7.5 mm, will increased dose of oral estradiol to 8mg daily and estradiol transdermal patches to 200 microgram daily .After 3 day will repeated monitoring and if endometrial thickness are more than or equal 7.5 ,in both group progesterone in oil 100 mg daily IM injection will be done. After 48-72 hours, between 1-3 embryo will transferred trans-cervically. Hormonal therapy will continued till pregnancy test after 2 weeks. In case of a positive pregnancy test and pregnancy documentation by sonography , hormonal therapy will continue till 10th weeks of pregnancy. Primary outcome: endometrial thickness Secndry outcomes: chemical pregnancy, clinical pregnancy, endometrial preparation time, cycle cancellation rate

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012071910328N2**

Registration date: **2012-11-14, 1391/08/24**

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

Last update:

Update count: **0**

##### Registration date

2012-11-14, 1391/08/24

##### Registrant information

###### Name

Sima Janati

###### Name of organization / entity

Research and Clinical Center for Infertility, Dezful  
University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 4242 9781

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Research and Clinical Center for Infertility, Shahid  
Sadoughi University of Medical Sciences Yazd ,Iran

##### Expected recruitment start date

2012-04-01, 1391/01/13

##### Expected recruitment end date

2013-03-18, 1391/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of effect of transdermal estradiol and

estradiol valerate on endometrial receptivity in frozen-thawed embryo transfer cycles

#### Public title

Comparison of two protocol of endometrial preparation in thawed- embryo transfer cycles

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: female Exclusion criteria: FSH in day 3 of cycle more than 12 ; age below 20 and more than 40 years; bad quality vitrified/warmed embryo; polycystic ovarian syndrome ; endocrine or metabolic disorder;endometriosis ; egg donation

#### Age

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

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **90**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences,Yazd,Ir

##### Street address

Bouali Ave, Safayeh, Research and Clinical Center for Infertility, Yazd

##### City

Yazd

##### Postal code

#### Approval date

2012-03-15, 1390/12/25

#### Ethics committee reference number

3769

## Health conditions studied

### 1

#### Description of health condition studied

Infertility

#### ICD-10 code

N98.9

#### ICD-10 code description

Complication associated with artificial fertilization, unspecified

## Primary outcomes

### 1

#### Description

Endometrial thickness

#### Timepoint

10-20 days

#### Method of measurement

Measurement between two layers of endometrium by vaginal sonography

## Secondary outcomes

### 1

#### Description

Clinical pregnancy

#### Timepoint

4-5 weeks after embryo transfer

#### Method of measurement

Observation of fetal heart activity by transvaginal sonography

### 2

#### Description

Time of endometrial preparation

#### Timepoint

11-14 days

#### Method of measurement

Repeated vaginal sonography

### 3

#### Description

Cancelation rate of cycles

#### Timepoint

10-20 days

#### Method of measurement

Repeated vaginal sonography

### 4

#### Description

Chemical pregnancy

#### Timepoint

Two weeks after embryo transfer

#### Method of measurement

BHCG test

## Intervention groups

### 1

#### Description

In intervention group (45 patients), at the same time of menses will be applied 17-B estradiol transdermal patches 100 mcg every other day that each patch will be removed after four days. In both groups clinical monitoring by transvaginal ultrasound will be done on 11th day of menstruation to measure endometrial thickness. While endometrial thickness is less than 7.5 mm, will increase the dose of 17-B estradiol transdermal patches to 200 mcg daily. After 3 days will be repeated monitoring and while endometrial thickness is more than or equal to 7.5, 100 mg progesterone in oil daily IM injection will be done. After 48-72 hours, between 1-3 embryos will be transferred trans-cervically. Hormonal therapy will be continued till pregnancy test after 2 weeks. While pregnancy test is positive, 2-3 weeks after, sonography for observation of the fetal heart activity will be done. If pregnancy is documented with sonography, hormonal therapy will continue till 10th weeks of pregnancy.

#### Category

Treatment - Drugs

### 2

#### Description

In control group (45 patients), for endometrial preparation will be started from 2nd day of cycle with oral estradiol 6 mg daily. In both groups clinical monitoring by transvaginal ultrasound will be done on 11th day of menstruation to measure endometrial thickness. While endometrial thickness is less than 7.5 mm, will increase the dose of oral estradiol to 2mg each 6 hours. After 3 days will be repeated monitoring and while endometrial thickness is more than or equal to 7.5, 100 mg progesterone in oil daily IM injection will be done. After 48-72 hours, between 1-3 embryos will be transferred trans-cervically. Hormonal therapy will be continued till pregnancy test after 2 weeks. While pregnancy test is positive, 2-3 weeks after, sonography for observation of the fetal heart activity will be done. If pregnancy is documented with sonography, hormonal therapy will continue till 10th weeks of pregnancy.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Science, Yazd

##### Full name of responsible person

Dr. Sima Janati

##### Street address

Boali Ave, Safayeh, Research and Clinical Center for Infertility, Yazd

#### City

Yazd

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Wise Cancellor of Shahid Sadoughi University of Medical Sciences of Yazd, Research and Clinical Center

##### Full name of responsible person

Dr. Robab Davar

##### Street address

Bouali Ave, Safayeh, Research and Clinical Center for Infertility

##### City

Yazd

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Wise Cancellor of Shahid Sadoughi University of Medical Sciences of Yazd, Research and Clinical Center

##### 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 Yazd

##### Full name of responsible person

Dr. Sima Janati

##### Position

Assisted professor of Obstetrics and Gynecology, fellow ship of infertility in state of training

##### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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

**Full name of responsible person**

Dr. Robab Davar

**Position**

Associate professor of Obstetrics and Gynecology

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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

**Full name of responsible person**

Dr. Sima Janati

**Position**

Assisted professor of Obstetrics and Gynecology, fellow ship of infertility in state of training

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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*