

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 β -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
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Country

Iran (Islamic Republic of)

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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

Cancellation 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 applied 17-B estradiol transdermal patches 100 mcg 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 17-B estradiol transdermal patches to 200 mcg daily .After 3 day will repeated monitoring and while endometrial thickness are more than or equal 7.5 , 100 mg progesterone in oil 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. While pregnancy test is positive , 2-3 weeks after, sonography for observation of the fetal heart activity will done. If pregnancy document with sonography , hormonal therapy continue till 10th weeks of pregnancy.

Category

Treatment - Drugs

2

Description

In control group (45 patients), for endometrial preparation will started from 2nd day of cycle oral estradiol 6 mg daily. 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 2mg each 6 hours .After 3 day will repeated monitoring and while endometrial thickness are more than or equal 7.5 , 100 mg progesterone in oil 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. While pregnancy test is positive , 2-3 weeks after, sonography for observation of the fetal heart activity will done. If pregnancy document with sonography , hormonal therapy 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 Canceler of Shahid Sadoughi University of Medical Sciences of Yazd,Research and Clinical Centre

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 Canceler of Shahid Sadoughi University of Medical Sciences of Yazd,Research and Clinical Centre

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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Full name of responsible person

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Position

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fellow ship of infertility in state of training

Other areas of specialty/work

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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