Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 17ß-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 Secondry 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)

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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 qaulity 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 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 of17-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 Cente
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 Cente
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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Position
Assisted professor of Obstetrics and Gynecology, 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