

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 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**Street address**

First floor, Valiasr Hospital 2, Imam Khomeini Hospital, Keshavarz Blvd

City

Tehran

Postal code

14194

Phone

+98 21 6658 1616

Fax

+98 21 6658 1616

Email

amani162@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Reproductive Health Research Center

Full name of responsible person

Mina Jafarabadi

Position

Associate Professor

Other areas of specialty/work**Street address**

First floor, Valiasr Hospital 2, Imam Khomeini Hospital, Keshavarz Blvd

City

Tehran

Postal code

14194

Phone

+98 21 6658 1616

Fax

+98 21 6658 1658

Email

minajaf@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Vali Asr Reproductive Health Research Center

Full name of responsible person

Fedyeh Haghollahi

Position

Researcher

Other areas of specialty/work**Street address**

First floor, Valiasr Hospital 2, Imam Khomeini
Hospital, Keshavarz Blvd.

City

Tehran

Postal code

14194

Phone

+98 21 6658 1616

Fax

+98 21 6658 1658

Email

fedyeh_hagh@yahoo.com

Web page address

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