

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of pregnancy rate for the best method for endometrial preparation in natural and hormonal cycles for the transfer of freeze-thawed embryos in infertile patients

Protocol summary

Summary

The purpose of this study is to compare the clinical pregnancy rates of Natural and Hormonal cycle in frozen embryo transfer. The study will be clinical trial, randomization, single center and double blind. 200 patients of Akbar Abadi hospital infertility unit who are planning an FET cycle, will join this study. Inclusion criteria will be regular ovulatory cycles; the ages will be between 19 to 45; causes of infertility will be male factor, endometriosis, tubal factor and idiopathic; basal serum levels of FSH will be less than or equal to 10 IU/l with normal Prolactin and absence of uterine anomalies. Patients with oocyte donation will be excluded from this survey. All patients who meet the inclusion criteria will be included after being informed of study condition and filling the inform consent form; then will be divided in two groups randomly. The first group will be those with Natural cycle and second group will be Hormonal cycle. Natural cycles with 100 infertile patients will be studied based on the daily serum LH of the 10th cycle day. When the serum LH level will be decreasing, ovulation will occur 36 to 40 hours later. The embryo transfer will be scheduled 3 to 5 days after ovulation. In hormonal cycles, 4 to 6 mg of Estradiol Valerate tablet will be taken from day 3 of the cycle. This group on 12th cycle day will undergo transvaginal sonography (TVS) for evaluation of endometrial thickness and if at least endometrial thickness 8 mm observed and embryos 3 to 5 days later will be transferred. The same day SUPP Progesterone 400 mg (Cyclogest) twice daily will be started. The embryo transfer will be scheduled 3 to 5 days after starting progesterone. Primary outcome is chemical pregnancy rate that will be measured by Beta-HCG testing for 14 days after the embryo transfer. Other outcomes will be clinical pregnancy and endometrial thickness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081335670N1**
Registration date: **2017-10-08, 1396/07/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-08, 1396/07/16

Registrant information

Name

Fatemeh Ashtari

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pregnancy rate for the best method for endometrial preparation in natural and hormonal cycles for the transfer of freeze-thawed embryos in infertile patients

Public title

Comparing the rate of pregnancy of Natural cycle and Hormonal cycle in frozen embryo transfer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: regular cycle; causes of infertility are male factor; endometriosis; tubal factor; idiopathic; serum levels of FSH is less than or equal to 10 IU/l; normal Prolactin; no allergy to Estradiol and Progesterone; the absence of uterine anomalies
Exclusion criteria: patients with oocyte donation will be excluded from this plan

AgeFrom **19 years** old to **45 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **200****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization is based on close envelope method

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Postal code

۱۳۹۹۶۱۴۵۳۵

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.IUMS.REC 1395.9211290001

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Chemical pregnancy rate

Timepoint

14 days after embryo transfer

Method of measurement

Beta-HCG using lab kit

Secondary outcomes**1****Description**

clinical pregnancy rate

Timepoint

7 weeks after embryo transfer

Method of measurement

fetal heart rate in ultra sonography

2**Description**

Endometrial thickness

Timepoint

From the 12th day of the cycle, one day in between

Method of measurement

Measurement with transvaginal ultrasound

Intervention groups**1****Description**

Control group: Natural cycles with 100 infertile patients will be studied based on the daily serum LH of the 10th cycle day. When the serum LH level will be decreasing, ovulation will occur 36 to 40 hours later. The embryo transfer will be scheduled 3 to 5 days after ovulation

Category

Other

2

Description

Intervention group: In hormonal cycles, 4 to 6 mg of Estradiol Valerate tablet will be taken from day 3 of the cycle. This group on 12th cycle day will undergo transvaginal sonography (TVS) for evaluation of endometrial thickness and if at least endometrial thickness 8 mm observed and embryos 3 to 5 days later will be transferred.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbar Abadi hospital

Full name of responsible person

Fatemeh Ashtari

Street address

Shahid Akbar Abadi hospital, Molavi st, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Kazem Malakouti

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway, Tehran

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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 of Iran 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

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Ashtari

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Full name of responsible person

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Position

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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