Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the rate of pregnancy of Natural versus modified –natural cycle for endometrial preparation in frozen embryo transfer

Protocol summary

Study aim
Comparing the rate of pregnancy of Natural versus modified –natural cycle in frozen embryo transfer
Design
Single blinded randomized controlled clinical trial
Settings and conduct
Settings: Arash Women's Hospital Blinding: Single-blind (outcome assessor and data analyst)
Participants/Inclusion and exclusion criteria
Inclusion criteria: maximum age 38 years, regular menstrual cycles Exclusion criteria: PCO, endometriosis, FSH ≥ 12 IVF and Severe Male Factor
Intervention groups
Group1: will receive vaginal progesterone after positive urinary LH kit. Group 2: 5000 IU HCG injection IM state, after presenting endometrial thickness>7 mm and 17 mm dominant folicule in transvaginal sonography.
Main outcome variables
Chemical pregnancy rate, clinical pregnancy rate, abortion rate, implantation rate, ongoing pregnancy rate

General information

Reason for update
Correcting Outcome Variables and blindness
Acronym
IRCT registration information
IRCT registration number: **IRCT201607311556N92**
Registration date: **2016-08-24, 1395/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-01, 1400/09/10**
Update count: **1**
Registration date
2016-08-24, 1395/06/03

Registrant information
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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2016-08-22, 1395/06/01
Expected recruitment end date
2018-02-20, 1396/12/01
Actual recruitment start date
2016-08-22, 1395/06/01
Actual recruitment end date
2018-04-20, 1397/01/31
Trial completion date
2018-08-22, 1397/05/31

Scientific title
Comparing the rate of pregnancy of Natural versus modified –natural cycle for endometrial preparation in frozen embryo transfer

Public title
Comparing the rate of pregnancy of Natural versus modified –natural cycle in frozen embryo transfer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age below 38 Regular menstrual cycle Normal BMI The previous history of up to two IVF cycle
Exclusion criteria:

PCOD History of endometriosis (grade ≥3) according to AFS Abnormal uterin FSH ≥12 Sever male factor

Age

To **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Actual sample size reached: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients underwent FET according to a computer-generated concealed randomization list using the block randomization method. There were six blocks. The statistician prepared random treatment assignments in sealed envelopes to conceal the randomization list from all research staff involved in enrollment and assessment.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was designed as a single blinded study and the outcome investigators (infertility clinic’s midwife and the gynecologist who performed ultrasound assessments), and the statistician were unaware of the type of intervention until the end of the study.

Placebo

Not 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

Qods St, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2016-08-09, 1395/05/19

Ethics committee reference number

IR.TUMS.MEDICINE.RBC.1395.426

Health conditions studied

1

Description of health condition studied

In vitro fertilization

ICD-10 code

Z31.2

ICD-10 code description

In vitro fertilization

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

6 weeks of pregnancy

Method of measurement

Ultrasonography

2

Description

Abortion rate

Timepoint

During 20 weeks of pregnancy

Method of measurement

Ulthrasonography, B-HCG

3

Description

Chemical Pregnancy Rate

Timepoint

2 weeks after embryo transfer

Method of measurement

Blood Pregnancy Test (BHCG)

Secondary outcomes

1

Description

Implantation

Timepoint

Gestational sac in 5 weeks of pregnancy

Method of measurement

ultrasonography

2

Description

Ongoing Pregnancy Rate

Timepoint

12 weeks of gestation

Method of measurement

The rate of pregnancies that continued ≥12 weeks of gestation.

3

Description
Endometrial thickness
Timepoint
At regular intervals until the endometrial thickness reaches above 7 mm
Method of measurement
Transvaginal Ultrasound

4

Description
No. of embryos transferred
Timepoint
At the time of embryo transfer
Method of measurement
Embryologist's report

Intervention groups

1

Description
The control group(1): progestron pessary administration after positive urinary LH kit
Category
Treatment - Drugs

2

Description
5000 Iu HCG injection IM state, after presenting endometrial thickness>7 mm and 17 mm dominant follicule in trans-vaginal ultrasonography
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's hospital
Full name of responsible person
Dr Ladan Kashani
Street address
Arash women's hospital, Reslat highway, Tehranpars, Rashid Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical scinces/Vice chancellor for research
Full name of responsible person
Dr Akbar Fotoohi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical scinces/Vice chancellor for research
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Saedeh Aref
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available