

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 \geq 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 follicle 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

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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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): progesteron 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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1653915981

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kashani_ladan@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical sciences/Vice chancellor for research

Full name of responsible person

Dr Akbar Fotoohi

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Vice chancellor for research, Tehran University of Medical sciences

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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 sciences/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 scientific inquiries

Contact

Name of organization / entity
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Assistant professor
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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