

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The comparison of fertility outcome obtained from freeze embryo transfer in natural cycle and estrogen progesterone cycle for endometrial preparation

Protocol summary

Summary

All patients who meet the inclusion criteria are included after being informed of conditions of study and fill in the inform consent form and divided between two groups randomly: first group Natural cycle and second group Artificial cycle. All patients underwent transvaginal sonography in the 1-3 days of the cycle for initial assessment of endometrial thickness and rule out of ovarian cysts. The first group on 12th cycle day undergo TVS for evaluation of follicular size and if at least one dominant follicle ≥ 18 mm and endometrial thickness 8 mm observed one single dose HCG 10000 IU will be administered and embryos 4 days later will be transferred. The same day SUPP progesterone 400 mg (cyclogest) BD will be started. On the second group in the months before starting the transfer cycle from 21 days of luteal phase GnRh agonist (busereline Merck) at a dose of 0.5mg (500mcg) daily will be started. Then on the 2th day of the next cycle estradiol valerate 2mg daily will be started and to 8mg will be adjusted based on the endometrial thickening. On the 10-12th cycle day TVS for evaluation endometrium will be done and if $ET > 9$ mm was observed SUPP progesterone (cyclogest 400mg/BD) will be added for 3 days at the same time. The embryo transfer will be scheduled at 72 hours after starting progesterone. 14-16 days after embryo transfer BHCG will be done for all patients and for positive cases 6 weeks after transfer vaginal sonography will be done to see fetal heart.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031022795N3**

Registration date: **2016-04-03, 1395/01/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-03, 1395/01/15

Registrant information

Name

Marzieh Ghasemi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5581

Email address

drghasemi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of fertility outcome obtained from freeze embryo transfer in natural cycle and estrogen progesterone cycle for endometrial preparation

Public title

Comparison of fertility outcome in freeze embryo

transfer cycles with endometrial preparation by natural cycle or artificial cycle

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: regular menses; age between 18-40 years old; an ivf cycle less than two years ago; having atleast 2 freeze embryos. Exclusion criteria: abnormal uterine bleeding; any endometrial pathology; history of 3 previous IVF failure; any underlying disease; endometriosis; sever male factor infertility need to TESE and PESA.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, Keshavarz Blvd., Tehran,Iran

City

Tehran

Postal code

1417614411

Approval date

2015-03-21, 1394/01/01

Ethics committee reference number

IR.TUMS.REC.1394.2051

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

4 weeks after embryo transfer

Method of measurement

Find gestational sac on transvaginal sonography

Secondary outcomes

1

Description

chemical pregnancy rate in two group

Timepoint

two weeks after transfer for biochemical pregnancy

Method of measurement

BHCG for biochemical

2

Description

rate of abortion

Timepoint

12 weeks after transfer for abortion

Method of measurement

physical examination and trans vaginal sonography for abortion

3

Description

Clinical pregnancy rate

Timepoint

4weeks for clinical pregnancy

Method of measurement

trans vaginal sonography for clinical

4

Description

Live Birth Rate

Timepoint

24 weeks after transfer for live birth rate

Method of measurement

following of patients until 26 weeks in pregnancy for live birth rate

Intervention groups

1

Description

In the natural cycle group patients will be followed with several sonography for seeing dominant follicle more than 18 mm and then 10000 IU HCG will be administrated and 4 days later the embryos will be transferred

Category

Treatment - Drugs

2

Description

On the artificial group in the months before starting the transfer cycle from 21 days of luteal phase GnRh agonist (buserline Merck) at a dose of 0.5mg (500mgr) daily will be started. Then on the 2th day of the next cycle estradiol valerate 2mg daily will be started and to 8mg will be adjusted based on the endometrial thickening. on the 10-12th cycle day TVS for evaluation endometr will be done and if ET>9 mm was observed SUPP progesterone (cyclogest 400mg/BD) will be added for 3 days at the same time .The embryo transfer will be scheduled at 72 hours after starting progesterone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility ward, Shriati hospital

Full name of responsible person

Dr Marzieh Aghahosseini, Infertility fellowship,
Professor of obstetrics and gynecology

Street address

Shariati hospital, Jalal-Al -Ahmad intersection Kargar
Shomali, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Masud Yunesian

Street address

Tehran, Keshavarz Blvd, Tehran University of Medical
Sciences, Department of Research and Technology

City

Tehran

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

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

Tehran University of Medical Sciences

Full name of responsible person

Marzieh Ghasemi

Position

MD, Fellowship in infertility

Other areas of specialty/work

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Full name of responsible person

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Position

MD, Fellowship infertility

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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