Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of fertility outcome obtained from freeze embryo transfer in natural cycle and estrogen progestrone 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 endometral thickness and rule out of ovarian cysts . The first group on 12th cycle day undergo TVS for evaluation of follicular size and if atleast one dominant follicle >=18 mm and endometrial thickness 8 mm observed one single dose HCG 10000 IU will be administrated and embryos 4 days later will be transfered.The same day SUPP progestrone 400 mg (cyclogest) BD will be started. On the second group n the months before starting the transfer cycle from 21 days of luteal phase GnRh agonist (busereline 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 progestrone (cyclogest 400mg/BD) will be added for 3 days at the same time .The embryo transfer will be scheduled at 72 hours after starting progestrone .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 progestrone 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 (busereline 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 progestrone (cyclogest 400mg/BD) will be added for 3 days at the same time .The embryo transfer will be scheduled at 72 hours after starting progestrone

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 obestetrics 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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Person responsible for scientific inquiries

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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