Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of intrauterine hCG injection before embryo transfer on pregnancy rate in frozen embryo transfer cycles

Protocol summary

Study aim

Determining the effect of intrauterine hCG injection before embryo transfer on pregnancy rate in frozen embryo transfer cycles

Design

Clinical trial with parallel control group, randomized, phase 3 on 300 patients. Block randomization method will be used for randomization

Settings and conduct

Patients are studied in two groups at Shariati hospital in Tehran: After preliminary preparation of patients, the target group will be injected with 500 hCG units in the uterine cavity 4 minutes before embryo transfer, and the control group will be injected with 0.1 cc of media solution in the same way. In both groups, treatment with estradiol and progesterone will continue, and 2 weeks later a pregnancy test (hCG test) will be performed on the patients.

Participants/Inclusion and exclusion criteria

In this clinical trial , among women with infertility problems referred to Dr. Shariati Hospital in Tehran, women with frozen fetuses are included in the study. Inclusion criteria are: age 20 to 39 years; Good quality embryos A and B and the first frozen embryo transfer. exclusion criteria: More than 40 years old;Male infertility TESE (percutaneous aspiration of sperm from the epididymis) and PESA (extraction of sperm from the testis) and azoospermia; History of myomectomy; Existence of hydrosalpinx; Existence of fibroids with compressive effect on endometrium; Endometriosis

Intervention groups

The intervention group will inject 500 hCG units (volume 0.1 cc) into the uterine cavity on day 2-3 of menstruation, 4 minutes before embryo transfer, then the embryo will be transferred with grade A-B cleavage stage. The control group will receive 0.1 cc media solution instead hCG.

Main outcome variables

Presence of a pregnancy sac and the presence of a fetal heart in followed up ultrasound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110602006689N4**
Registration date: **2021-09-08, 1400/06/17**
Registration timing: **prospective**

Last update: **2021-09-08, 1400/06/17**
Update count: **0**

Registration date

2021-09-08, 1400/06/17

Registrant information

Name

Sedigheh Hosseinimousa

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 8810

Email address

hoseinimosa@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of intrauterine hCG injection before embryo transfer on pregnancy rate in frozen embryo transfer cycles

Public title
The effect of intrauterine hCG injection before embryo transfer on pregnancy rate in frozen embryo transfer cycles

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-39 Embryo with grade A and B First transfer
Exclusion criteria:
Age 40 or above 40 Male infertility TESE or PESA and azospermia History of myomectomy Hydrosalphinx Myoma with compressive effect Endometriosis

Age
From **20 years** old to **39 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: We use the block randomization method to randomize subjects into groups that result in equal sample sizes. We use the block size 4. From the following blocks, first select 1 by accident and divide the samples into two groups according to the order and fill the blocks A for intervention and B for placebo B A B A 2) B B A A 1) B A A B 4) A B B A 3) A A B B 6) A B A B 5)

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single-blind and the participants would not know about the type of treatment.

Placebo
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
Ethics Committee, Tehran University of Medical Sciences, Poorsina Street, Tehran
City
Tehran
Province
Tehran
Postal code
1417653761

Approval date
2021-03-13, 1399/12/23

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.1258

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
Pregnancy

Timepoint
2 weeks after embryos transfer

Method of measurement
Ultrasound

Secondary outcomes

1

Description
Clinical pregnancy rate

Timepoint
From 12 weeks

Method of measurement
Heart rate presence on ultrasound

Intervention groups

1

Description
Intervention group: in 2-3rd day of mensuration period, after baseline ultrasound, ensuring uterine and ovarian suppression and ovarian pathologies role out, 2 mg estradiol will be started every 12 hours and will be adjusted based on endometrial response. After preparing the endometrium, the thickness of the endometrium reaches the appropriate level by performing serial

ultrasound, the participants receives progesterone suppositories for 4 days and 4 minutes before embryo transfer, 500 units of hCG (volume 0.1 cc) will be injected into the uterine cavity with Cook transfer catheter, then the embryo will be transferred with grade A-B cleavage stage.

Category

Treatment - Drugs

2

Description

Control group: in 2-3rd day of mensuration period, after baseline ultrasound, ensuring uterine and ovarian suppression and ovarian pathologies role out, 2 mg estradiol will be started every 12 hours and will be adjusted based on endometrial response. After preparing the endometrium, the thickness of the endometrium reaches the appropriate level by performing serial ultrasound, the participants receives progesterone suppositories for 4 days and 4 minutes before embryo transfer, 0.1 cc of media solution will be injected into the uterine cavity with a Cook transfer catheter and then the embryo will be transferred with grade A-B cleavage step.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Unit, Shariati Hospital

Full name of responsible person

Dr. Sedighe Hosseinimousa

Street address

Department of Infertility, Shariati Hospital, Tehran University of Medical Sciences, North Karegar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhoondzadeh

Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Keshavarz Boulevard, Tehran

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ivfshariati69@gmail.com

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

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

Dr Sedighe Hoseinimosa

Position

Infertility Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
Starting 9 months after publication

To whom data/document is available
Only available for people working in academic institutions

Under which criteria data/document could be used
No other condition is considered

From where data/document is obtainable
hoseinimosa@sina.tums.ac.ir

What processes are involved for a request to access data/document
1 year

Comments