

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison the Effect of intra Uterin and Intra Muscular HCG Injection 3 Days Before Transfer in frozen Thawed Embryo Transfer Cycles in Patients with Repeated Implantation Failure

Protocol summary

Study aim

Influence of intramuscular and intrauterine HCG 3 days before embryo transfer on pregnancy outcome of frozen thawed embryo transfer cycle(FET) in patient with recurrent implantation failure.

Design

three arm parallel 70 patients group randomized through random digits number

Settings and conduct

Endometrial preparation will be done from second day of cycle with 6mg daily estradiol in patient with recurrent implantation failure who are candidate for frozen thawed embryo transfer and serial sonography will be done from 12th day of cycle ;when thickness reaches 7mm or more and patients have including criteria they will divided into 3 groups through ;in control group we just prescribe 400mg daily progesterone for 3 days and in first case group they will receive 500 unit intramuscular HCG along with 400mg progesterone ,in second case group they will receive 500 unit intrauterine HCG along with 400mg progesterone ,72 hours later all pateints will be transferred maximum 2 cleaved embryo; serum BHCG will be checked 2weeks later and if it is positive, vaginal sonography must be done for identification of gestational sac with fetal heart beat.

Participants/Inclusion and exclusion criteria

including criteria:20-40 years old infertile patient with recurrent implantation failure who are candidate for transferring frozen thawed embryo and have adequate endometrial thickness excluding criteria: uterus malformation or adhesion, sever andometriosis or adenomyosis

Intervention groups

20-40 years old infertile woman with recurrent implantation failure who are candidate for frozen thawed embryo transfer and have appropriate endometrium received 500 unit intramuscular and intrauterine HCG

along with progesterone

Main outcome variables

chemical pregnancy; clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200305046702N1**

Registration date: **2020-10-27, 1399/08/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-27, 1399/08/06**

Update count: **0**

Registration date

2020-10-27, 1399/08/06

Registrant information

Name

Zhhreh Pezeshkpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3824 7085

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of intra Uterin and Intra Muscular HCG Injection 3 Days Before Transfer in frozen Thawed Embryo Transfer Cycls in Patients with Repeated Implantation Failure

Public title

Effect of HCG Injection in Frozen Thawed Embryo Transfer Cycls in Patients with Repeated Implanttion Failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20-40 years old infertile patient with history of two or more previous impiantation failure candidate for frozen thawed embryo transfer

Exclusion criteria:

uterous malformation-sever endometriosis and adenomyosis-uterus adhesion- egg donation

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

simple individual randomization with computerized digit number table. Randomization will be performed with simple method and random numbers generated by computer soft ware(Stat trek soft ware) wich choose the random numbers. then, we consider the specific numbers for both groups for example: the even numbres are for intervention group and the odd numbres are for the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Research and Clinical Center for Infertility(Yazd Reproductive Sciences Institut

Street address

Research and Clinical Center for Infertility, BouAli avenue, Safaieye

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2020-06-20, 1399/03/31

Ethics committee reference number

IR.SSU.RSI.REC.1399.007

Health conditions studied**1****Description of health condition studied**

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

implantation

Timepoint

4weeks after embryo transfer

Method of measurement

observation of gestational sacs by transvaginalultrasonography

2**Description**

Chemical poregnancy

Timepoint

2weeks after embryo transfer

Method of measurement

serum BHCG

Secondary outcomes**1****Description**

clinical pregnancy

Timepoint

2 weeks after positive BHCG

Method of measurement

vaginal sonography

Intervention groups

1

Description

Intervention group : Endometrial preparation will be done for 20-40 years old infertile woman with recurrent implantation failure who are candidate for frozen thawed embryo transfer from second day cycle with 6 mg daily estradiol and serial sonography will be done from 12th day of cycle ; when thickness reaches 7 mm ,they receive 500 unit intramuscular HCG along with 400 mg progesterone , 3 days before embryo transfer will be done.

Category

Treatment - Drugs

2

Description

Intervention group : Endometrial preparation will be done for 20-40 years old infertile woman with recurrent implantation failure who are candidate for frozen thawed embryo transfer from second day cycle with 6 mg daily estradiol and serial sonography will be done from 12th day of cycle ; when thickness reaches 7 mm ,they receive 500 unit intrauterine HCG along with 400 mg progesterone , 3 days before embryo transfer will be done.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and Clinical Center for Infertility(Yazd Reproductive Sciences Institute)

Full name of responsible person

Dr Raziye Firouzabadi

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Yazd,Safaeiyeh,Bouali ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Masoud Mirzaei

Street address

Safaeiye-Bouali ave-Research and Clinical Center for Infertility

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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

Yazd 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

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Raziye Firouzabadi

Position

Obstetrician and Gynecologist .Infertility and IVF Fellowship(Professor)

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Raziye Firouzabadi

Position

Obstetrician and Gynecologist .Infertility and IVF Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Zhoreh Pezeshkpour

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information exist

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available