

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Influence of growth hormone supplementation on pregnancy outcome of patients undergoing frozen thawed embryo transfer(FET)

Protocol summary

Study aim

Influence of growth hormone supplementation on pregnancy outcome of frozen thawed embryo transfer cycle(FET)

Design

non randomized 2 arm parallel group with 50 patients

Settings and conduct

Endometrial preparation will be done from second day of cycle with 6mg daily estradiol in patient 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 2 groups ;in control group we just prescribe 400mg daily progesterone for 3 days and in case group they will receive 1.2 mg growth hormone 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 who will transfered frozen thawed embryo and have adequate endometrial thickness excluding criteria: uterus malformation or adhesion, sever andometriosis or adenomyosis and recurrent implantation failure

Intervention groups

20-40 years old infertile woman who are candidate for frozen thawed embryo transfer and have appropriate endometrium received 1.2 mg daily growth hormone along with progesterone

Main outcome variables

chemical pregnancy; clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091018002604N5**

Registration date: **2020-03-02, 1398/12/12**

Registration timing: **retrospective**

Last update: **2020-09-16, 1399/06/26**

Update count: **1**

Registration date

2020-03-02, 1398/12/12

Registrant information

Name

Robab Davar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 7085

Email address

davar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-02-03, 1398/11/14

Actual recruitment start date

2019-09-22, 1398/06/31

Actual recruitment end date

2020-02-03, 1398/11/14

Trial completion date

2020-03-04, 1398/12/14

Scientific title

Influence of growth hormone supplementation on pregnancy outcome of patients undergoing frozen thawed embryo transfer(FET)

Public title

Influence of adding growth hormone in frozen embryo transfer cycle outcome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20-40 years old infertile patient candidate for frozen thawed embryo transfer

Exclusion criteria:

uterus malformation-sever endometriosis and adenomyosis-uterus adhesion-recurrent implantation failure

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: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description**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

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Yazd

Province

Yazd

Postal code

8916877391

Approval date

2019-09-14, 1398/06/23

Ethics committee reference number

IR.SSU.RSI.REC.1398.025

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

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

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

chemical pregnancy

Timepoint

2weeks after embryo transfer

Method of measurement

serum BHCG

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

clinical pregnancy

Timepoint

2weeks 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 who are candidate for frozen thawed embryo transfer from second day of cycle with 6 mg daily estradiol and serial sonography will be done from 12th day of cycle ;when thickness reaches 7 mm ,they receive 1.2 mg daily growth hormone along with 400 mg progesterone for 3 days and then embryo transfer will be done.

Category

Treatment - Drugs

2**Description**

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

Category

Treatment - Drugs

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.Robab Davar

Street address

Yazd,Safaeiyeh,Bouali ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Shahid Sadoughi University of Medical Science,Yazd,Iran

Full name of responsible person

Robab davar

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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

Vice chancellor for research,Shahid Sadoughi University of Medical Science,Yazd,Iran

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

Robab Davar M.D.

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

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Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Other areas of specialty/work
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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