

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of single dose of GnRH-agonist on pregnancy outcome in frozen-thawed embryo transfer cycles

Protocol summary

Study aim

the additional GnRH agonist administered at the time of implantation for luteal phase support in FET cycles improves the pregnancy outcome in frozen-thawed embryo transfer cycles (FET) cycles

Design

prospective parallel single blind controlled trial on 200 patients. for randomization was computerized with randomization table

Settings and conduct

Patients were administered estradiol valerate 6 milligrams daily and ASA 80 mg from day 2 of the cycle. vaginal sonography was done on day ; since the endometrial thickness reached 8 mm, daily vaginal progesterone suppositories (total dose 800 mg daily) was administered . Randomization was done on the day of embryo transfer by a computer-generated table. Blindness was done for researchers. Patients were divided to group 1 (n=100) to whom a single dose of GnRH agonist (0.1 mg triptorelin) was administered three days after transfer and group 2 (n=100) , who did not receive agonist. Both groups received daily vaginal progesterone suppositories (800 mg daily) plus estradiol valerate (6 mg dai-ly)

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients in frozen-thawed embryo transfer cycle who have frozen embryo due to previous OHSS or supernumerary frozen embryos age of 18 to 40 years; exclusion: patients below the age of 18 and over 40 years; oocyte recipients; patients who had systemic or endocrine disorders ; submucous fibroids or intrauterine adhesions with or without history of previous surgery

Intervention groups

patients in frozen-thawed embryo transfer cycle

Main outcome variables

primary outcome measure was clinical pregnancy rate. secondary outcome measures were implantation rate, chemical , ongoing pregnancy rate and abortion rate

General information

Reason for update

defect in previous data

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031021420N1**

Registration date: **2015-04-12, 1394/01/23**

Registration timing: **retrospective**

Last update: **2021-03-08, 1399/12/18**

Update count: **1**

Registration date

2015-04-12, 1394/01/23

Registrant information

Name

Maryam Farid Mojtahedi

Name of organization / entity

Arash women hospital, clinic for infertility, Tehran university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 8755

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Yazd University of Medical Sciences

Expected recruitment start date

2014-04-03, 1393/01/14

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

2014-04-03, 1393/01/14

Actual recruitment end date

2015-01-01, 1393/10/11

Trial completion date
2015-01-01, 1393/10/11

Scientific title
Effect of single dose of GnRH-agonist on pregnancy outcome in frozen-thawed embryo transfer cycles

Public title
GnRH agonist administration in assisted reproductive program

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patients in frozen-thawed embryo transfer cycle who have freezed embryo due to previous OHSS or supernumerary freezed embryos age of 18 to 40years
Exclusion criteria:
 patients below the age of 18 and over 40 years, , , endometriosis, oocyte recipients patients who had systemic or endocrine disorders such as diabetes mellitus and thyroid disorders submucous fibroids or intrauterine adhesions with or without history of previous surgery

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
 Target sample size: **221**
 Actual sample size reached: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
simple, randomization table

Blinding (investigator's opinion)
Single blinded

Blinding description
participants, data evaluators

Placebo
Not used

Assignment
Parallel

Other design features
A computer-generated randomization table was created for the study population .Allocation concealment was ensured by the use of sealed envelopes on the day of embryo transfer

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Shahid Sadoughi University of Medical Sciences

Street address

Bouali Ave, Safaeyeh

City

yazd

Province

Yazd

Postal code

8916877391

Approval date

2014-06-22, 1393/04/01

Ethics committee reference number

314

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

clinical pregnancy

Timepoint

28 days after transfer

Method of measurement

vaginal sonography

Secondary outcomes

1

Description

chemical pregnancy

Timepoint

14 days after transfer

Method of measurement

BHCG test

Intervention groups

1

Description

intervention group:a single dose of GnRH agonist(0.1 mg triptorelin) was administered three days after transfer

Category

Treatment - Drugs

2**Description**

Control group do not receive triptoreline0.1mg.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Yazd reserch and clinical center for infertility

Full name of responsible person

abbas aflatoonian

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Bouali Avenue, Safayeh

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Email

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Yazd Research and Clinical center for infertility

Full name of responsible person

Alimohammad Abdoli

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Email

info@yazd-rsi.ir

Web page address

http://ssu.ac.ir/cms

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd Research and Clinical center for infertility

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**

Yazd Reserch and Clinical center for infertility

Full name of responsible person

Dr.Robab Davar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd Reaserch and Clinical Center for infertility

Full name of responsible person

Dr. Maryam faridMojtahedi

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Yazd Reaserch and Clinical Center for infertility
Full name of responsible person
Dr.Robab Davar
Position
Assoiate Professor
Latest degree
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Other areas of specialty/work
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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

only some data like main outcomes can be shared.

When the data will become available and for how long

from 1395

To whom data/document is available

academic and scientific researchers

Under which criteria data/document could be used

no specific circumstances

From where data/document is obtainable

m_fmojtahedi@yahoo.com maryam farid Mojtahedi

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

by e-mail

Comments