

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Effects of GnRH agonist for luteal phase support in assisted reproductive cycles

Protocol summary

Study aim

Influence of GnRH agonist in luteal phase support for assisted reproductive techniques

Design

a clinical trial with two parallel arms non randomized patient group

Settings and conduct

20-39 years old infertile normal responder patients candidate for IVF, divide to two non randomized parallel group, in case group we inject 0.1mg triptorelin in days 0-3-6 plus 400 mg intravaginal cyclogest twice daily. in control group we just prescribe 400 mg intra vaginal cyclogest twice daily for luteal phase support. 2 weeks after transferring serum BHCG will check and 2 weeks after positive BHCG, vaginal sonography for checking gestational sac and fetal heart rate will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Age between 20-39 years-fresh embryo transfer cycles- Exclusion criteria : low ovarian response ovarian hyper stimulation-oocyte donation-severe endometriosis

Intervention groups

Infertile women with normal ovarian response that subcutaneous inject of triptorelin 0/1 mg 0-3-6 days after fresh transfer

Main outcome variables

Chemical pregnancy-clinical pregnancy

General information

Reason for update

Updating the trial according to the last changes in methods

Acronym

IRCT registration information

IRCT registration number: **IRCT20110509006420N20**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-07, 1400/03/17**

Update count: **3**

Registration date

2020-03-11, 1398/12/21

Registrant information

Name

Maryam Eftekhar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35182470856

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eftekhar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-01, 1398/10/11

Expected recruitment end date

2020-03-30, 1399/01/11

Actual recruitment start date

2020-01-01, 1398/10/11

Actual recruitment end date

2020-03-30, 1399/01/11

Trial completion date

2020-05-15, 1399/02/26

Scientific title

Effects of GnRH agonist for luteal phase support in assisted reproductive cycles

Public title

Effects of GnRH agonist for luteal phase support

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 20-39 years fresh embryo transfer cycles HCG - triggered cycles

Exclusion criteria:

Absence of good quality embryo Ovarian hyper stimulation (more than 18 mature follicles with size more than 14 mm during ovarian stimulation) or estradiol level in trigger days more than 4000 pmol/l Severe male factor

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

Actual sample size reached: **168**

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 Yazd Research and Clinical Center for infertility, Shahid Sadoughi University of

Street address

Bouali Ave, Safaeiyeh

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2019-12-29, 1398/10/08

Ethics committee reference number

IR.SSU.RSI.REC.1398.043

Health conditions studied

1

Description of health condition studied

female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

serum BHCG

2

Description

clinical pregnancy

Timepoint

6 weeks after embryo transfer

Method of measurement

sonography

Secondary outcomes

empty

Intervention groups

1

Description

taking 0/1 mg triptorelin in 0-3-6 days after fresh emeryo transfer plus 400mg vaginal cyclogest twice daily for luteal phase support.

Category

Treatment - Drugs

2

Description

Control group: taking 400mg vaginal cyclogest twice daily for luteal phase support.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Research and Clinical Center for Infertility

Full name of responsible person

Dr. Maryam Eftekhari

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Boali Ave., Safayeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
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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
Yazd University of Medical Sciences
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Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

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