

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of gonadotropin-releasing hormone analogue (GnRh-a) for triggering and luteal phase support in antagonist -in vitro fertilization cycles (IVF) in normal responders and comprission with standard protocol

Protocol summary

Study aim

Effect of Gonadotropin realeasing hormon aganoist(GnRH-a)for triggering and luteal phase support in IVF cycles

Design

This double blinded randomized clinical trial study is done in 72 antagonist IVF cycles in women aged 20-40 years in Taleghani hospital. After taking consent form patients will arrange in stydy or control group

Settings and conduct

This study is done in 72 antagonist based cycles performed in women aged 20-40 years in in vitro fertilization(IVF) unit of Taleghani hospital. Stimulation will be done on 3th menstrual cycle. Final oocyte maturation in GnRH-a groups will trigger with single double bolus triptorelline (0.1 mg each) . Double bolus UHCG (5000 IU each) will be prescribed in control group. Subsequently, luteal support will be done with subcutaneously triptorelline (GnRH-a group) or intramuscular progesterone100mg/day (P supplementation group).

Participants/Inclusion and exclusion criteria

Inclusion criteria:Age : 20-40 years BMI: 20-30 Fresh embryo transfer cycles serum FSH of third menstrual day below 10 and absence of low ovarian response Exclusion criteria:Failed fertilization Sever endometriosis Decreased ovarian reserve Absence of good quality embryo Ovarian stimulation hyper stimulation (more than 18 mature follicles during ovarian stimulation)

Intervention groups

Subcutaneous injection of triptorelline .2 mg and continue .2mg/BD for luteal phase support

Main outcome variables

Oocyte number- Clinical pregnancy -Chemical pregnancy - Abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160722029027N7**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-08, 1398/04/17**

Update count: **0**

Registration date

2019-07-08, 1398/04/17

Registrant information

Name

Leila Nazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

Email address

nazari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of gonadotropin-releasing hormone analogue (GnRh-a) for triggering and luteal phase support in antagonist -in vitro fertilization cycles (IVF) in normal responders and comparison with standard protocol

Public title

Effect of Gonadotropin-releasing hormone analogue(GnRh-a) for in vitro fertilization cycles (IVF)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 20-40 years normal respondering in IVF cycles Body mass index between 20-30 Fresh embryo transfer cycles Serum FSH of third menstrual day below 10 and absence of low ovarian response according bologna criteria

Exclusion criteria:

Failed fertilization Sever endometriosis Decreased ovarian reserve. Unwillingness to continue Absence of good quality embryo Ovarian stimulation hyper stimulation (more than 18 mature follicles during ovarian stimulation)

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects were assigned into two groups, using permuted block randomization method with size of block of two. Package block rand in R statistical software was used for preparing randomization list.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is double-blind study, that the participants do not know which of the two control or test groups belong, and also the observers (researchers) do not know who the group is.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yaman St, Chamran highway

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2018-09-30, 1397/07/08

Ethics committee reference number

IR.SBMU.REC.1397.029

Health conditions studied

1

Description of health condition studied

Noninflammatory disorders of female genitalia tract

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

4 weeks after embryo transfer

Method of measurement

Transvaginal Ultrasound

2

Description

Chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

serum β HcG test

3

Description

OOcyte number

Timepoint

After ovarian puncture

Method of measurement

Evaluation with reproductive biologist after ovarian puncture

Secondary outcomes

1

Description

Ongoing pregnancy

Timepoint

10 weeks after embryo transfer

Method of measurement

Fetal heart beat in ultrasound

2

Description

Abortion rate

Timepoint

Loss of pregnancy before 20 weeks

Method of measurement

Ultrasonography

Intervention groups

1

Description

Intervention group: Subcutaneous injection of Triptorelin(0/2 mg each of them 0/1 mg variopeptyl company) for trigger of follicle only single dose(on triggering day)

Category

Treatment - Drugs

2

Description

Second intervention group:Continue injection of Triptorelin 0/2mg/BD (each of them 0/1 mg variopeptyl company) until 2 weeks after embryo transfer

Category

Treatment - Drugs

3

Description

Control group:Intramuscular bolus injection of UHCG 10000 IU (Pregnyl ® 5000 I.U. powder for solution for injection)for trigger of follicle only single dose(on triggering day)

Category

Treatment - Drugs

4

Description

Second control group: Continue injection of progesterone two ampula daily(Iran hormon - each of ampula 50 mg) until 2 weeks after embryo transfer

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

IVF infertility & IVF ward of Talghani Hospital

Full name of responsible person

Hashemi Teibeh

Street address

Shahid Beheshti University of medical science

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 2558

Email

Hashemit89@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences,
Yaman st., Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 2558

Email

nazari@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hashemi Teibeh

Position

Flow ship of infertility

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Shabih Khani Hospital .Shahid Beheshti St

City

Kashan

Province

Isfahan

Postal code

8714715555

Phone

+98 31 5546 0180

Email

hashemit89@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Nazari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Taleghani hospital, Yaman st., Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 2558

Email

nazari@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hashemi Teibeh

Position

Flow ship of infertility

Latest degree

Subspecialist

Other areas of specialty/work

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City

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Province

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Postal code

8714715555

Phone

+98 31 5546 0180

Email

hashemit89@yahoo.com

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

Chemical pregnancy-Clinical pregnancy-Ongoing pregnancy-Abortion - oocyte number

When the data will become available and for how long

Without restriction

To whom data/document is available

All researchers

Under which criteria data/document could be used

With permission from the author responsible

From where data/document is obtainable

Email to author responsible

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

Email to author responsible

Comments