# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Effect of gonadotropin-releasing hormone analogue (GnRh-a ) for triggering and luteal phase support in antagonist –in vitro fertillization 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 subcutaneousely triptorelline (GnRH-a group) or intramuscular progestrone100mg/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

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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 fertillization cycles (IVF) in normal responders and comprission with standard protocol

**Public title**
Effect of Gonadotropin-releasing hormone analogue( GnRh-a ) for in vitro fertillization 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 βHcG 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 variopepty 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 progestrone 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
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Afshin Zarghi
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Shahid Beheshti University of Medical Sciences, Yaman st., Velenjak, Chamran highway
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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

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## Person responsible for scientific inquiries

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Leila Nazari

**Position**
Assistant professor

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Subspecialist

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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Hashemi Teibeh

**Position**
Flow ship of infertility

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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**
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**