

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effects of GnRH agonist for luteal support on improvement of IVF/ICSI cycles

#### Protocol summary

##### Study aim

This study was designed to evaluate the effectiveness of GnRh agonist for luteal support on improvement of intracytoplasmic sperm injection (ICSI) cycles.

##### Design

240 infertile patients who candidate ICSI with normal ovarian response are recruited into the study in two groups according to randomization method. Subcutaneous injection of 0.1 mg Triptorelin or placebo is performed 6 and 9 days after ICSI. Luteal support is performed for all participants as a same protocol (Vaginal Cyclogest 400 mg twice/day). Chemical and clinical pregnancy rate and abortion rate will be analyzed.

##### Settings and conduct

This clinical trial is performed in Infertility and IVF ward, Taleghani hospital

##### Participants/Inclusion and exclusion criteria

Age between 20-38 years old; body mass index (BMI) between 20-30; fresh embryo transfer cycles; 3rd menstrual day serum FSH below 10; absence of low ovarian response

##### Intervention groups

Intervention group: subcutaneous injection of Triptorelin (0.1 mg) 6 days after ICSI. Control group: subcutaneous injection of placebo 6 days after ICSI.

##### Main outcome variables

Chemical pregnancy; clinical pregnancy; ongoing pregnancy; abortion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160722029027N6**

Registration date: **2018-09-20, 1397/06/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-20, 1397/06/29**

Update count: **0**

##### Registration date

2018-09-20, 1397/06/29

##### 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

2018-03-21, 1397/01/01

##### Expected recruitment end date

2018-09-21, 1397/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of GnRH agonist for luteal support on improvement of IVF/ICSI cycles

##### Public title

Effects of GnRH agonist for luteal support on improvement of IVF/ICSI cycles

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age between 20-38 years old Body mass index (BMI) between 20-30 Fresh embryo transfer cycles 3rd menstrual day serum FSH below 10 Absence of low ovarian response according Bologna Criteria

**Exclusion criteria:**

Unwillingness to continue Absence of good quality embryo Ovarian hyper stimulation (more than 18 mature follicle during ovarian stimulation)

**Age**

From **20 years** old to **38 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **240**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling was randomized . In this method, we use the numerical random number table to choose the numbers, for example, if the sample size is two digits. First, select a two-digit number completely randomly, for example by placing the pencil tip, and then go ahead and select two-digit numbers to get the required number.

**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**

کمیته اخلاق دانشگاه علوم پزشکی شهید بهشتی

**Street address**

Velenjak, Yaman St, Chamran highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2018-01-26, 1396/11/06

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1396.994

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

Noninflammatory disorders of female genital 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 BHCG

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

Ongoing pregnancy

**Timepoint**

10 weeks after embryo transfer

**Method of measurement**

Fetal heart beat in ultrasound

**2****Description**

Abortion

**Timepoint**

Before 20 weeks of pregnancy

**Method of measurement**

Fetal demise before 20 weeks of gestation

**Intervention groups**

## 1

### Description

Intervention group: Subcutaneous injection of Triptorelin (0.1 mg) 6 and 9 days after ICSI

### Category

Treatment - Drugs

## 2

### Description

Control group: Subcutaneous injection of placebo(Normal saline) 6 and 9 days after ICS

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

IVF Infertility and IVF ward of Talghani hospital

#### Full name of responsible person

Leila Nazari

#### Street address

Yaman St., Velenjak, Chamran highway

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Tehran

#### Province

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1983969411

#### Phone

+98 21 2243 2558

#### Email

nazari@sbmu.ac.ir

## 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

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#### Phone

+98 21 2243 2558

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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

Leila Nazari

#### Position

Assistant professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

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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

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

### Data Dictionary

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

### Title and more details about the data/document

Chemical pregnancy-Clinical pregnancy-Ongoing pregnancy-Abortion

### 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

## Person responsible for updating data

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Leila Nazari

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