

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Comparison of Long protocol And Agonist-Antagonist protocol in the infertile normal responder patients undergoing ICSI cycles

#### Protocol summary

##### Summary

Comparison of Long and Agonist-Antagonist protocols for ovarian stimulation in normal responder patients undergoing Intra Cytoplasmic Sperm Injection . Randomized clinical trial. Under study population: Infertile normal responder patients referred to infertility clinic for ovarian stimulation under treatment of ICSI. Inclusion criteria: normal responder; BMI less than 30 . Exclusion criteria: low responder; high responder patients. In this study patients divided into two groups: In one group patients treating with Long protocol and other group treating with Agonist-Antagonist protocol. Sixty patients are in each group. After IVF, the results checked in short time and long time and effectiveness of these two protocol checked in clinical and chemical pregnancy.

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2016-01-14, 1394/10/24

##### Expected recruitment end date

2016-05-13, 1395/02/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016022326711N1**

Registration date: **2016-04-11, 1395/01/23**

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

Last update:

Update count: **0**

##### Registration date

2016-04-11, 1395/01/23

##### Registrant information

##### Name

fateme fakhar moghadam

##### Name of organization / entity

tehran university

##### Country

Iran (Islamic Republic of)

##### Phone

##### Scientific title

Comparison of Long protocol And Agonist-Antagonist protocol in the infertile normal responder patients undergoing ICSI cycles

##### Public title

Comparison of Long protocol And Agonist-Antagonist protocol in the infertile normal responder patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: normal responder infertile patients included (It means age less than 40 and normal ovarian reserve( 6<AFC<12 ) accompanying with 3.5>AMH>1); also patients had good response to previous ovarian stimulation: BMI more than 30 . Exclusion criteria: low responder patients; high responder patients; using donated oocyte and donated egg; single ovary; endometriosis; if patient's husband need to use TESE and PESA.

##### Age

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

**Street address**Tehran University of Medical Sciences, Keshavarz  
BLVD, Tehran**City**

Tehran

**Postal code****Approval date**

2016-01-13, 1394/10/23

**Ethics committee reference number**

IR.TUMS.REC.1394.1647

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

Infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

**Primary outcomes****1****Description**

Number of oocyte metaphase 2

**Timepoint**

After ovarian puncture

**Method of measurement**

Microscope- by counting oocyte

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

Age

**Timepoint**

Chronological age

**Method of measurement**

Birth Certificate - year

**2****Description**

time of infertility

**Timepoint**

At first

**Method of measurement**

Interviews with patient - year

**3****Description**

Type of infertility

**Timepoint**

At first

**Method of measurement**Interviews with patient - Infertility divided in two groups:  
primary (no pregnancy history) and secondary**4****Description**

Chemical pregnancy

**Timepoint**

Two weeks after transfer

**Method of measurement**

Blood test - bhcg titration

**5****Description**

Clinical pregnancy

**Timepoint**

Four weeks after transfer

**Method of measurement**Vaginal sonography - View gestational sac and fetal  
heart rate**6****Description**

The number of matured follicle

**Timepoint**

Before puncture

**Method of measurement**Vaginal sonography - The number of matured oocyte  
with size of 18mm or more

## 7

### **Description**

The number of antral follicle

### **Timepoint**

At first

### **Method of measurement**

Vaginal sonography - The number of antral follicle with size of 2-9 mm in follicular phase.

## 8

### **Description**

The number of punctured oocyte

### **Timepoint**

After puncture

### **Method of measurement**

Microscope - The number of punctured oocyte.

## 9

### **Description**

The number of fetus

### **Timepoint**

After puncture

### **Method of measurement**

Microscope-The number of fetuses after injection.

## 10

### **Description**

The number of transferred fetus

### **Timepoint**

In the time of transfer

### **Method of measurement**

Microscope - The number of fetuses transfer in uterine.

## 11

### **Description**

The days stimulation

### **Timepoint**

At first of cycle

### **Method of measurement**

Documents - The number of days that using gonadotropin

## 12

### **Description**

Endometrial thickness

### **Timepoint**

Before transfer

### **Method of measurement**

Vaginal sonography - mm

## 13

### **Description**

BMI

### **Timepoint**

At first

### **Method of measurement**

Examination of patient - Dividing weight in kg by the

square of one's height in cm

## 14

### **Description**

The number of drug used

### **Timepoint**

In the end of treatment

### **Method of measurement**

Documents - The number of drugs using for ovarian stimulation.

## **Intervention groups**

### 1

#### **Description**

In Agonist -Antagonist protocol in second day of cycle agonist GNRH (DECAPEPTYL0.1MG)used SC for 3 days and then gonadotropin (Gonal-f ) administered. After 6 days vaginal sonography done frequently and when one 14 mm follicle appears in sonography , antagonist GNRH (cerotide) used SC until two 18mm follicles appeared .Then HCG in 5000 unit injected IM and after36 hours oocytes punctured.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

In Long protocol in second or third day of cycle OCP started for 21 days. In Mid-luteal phase agonist GNRH (SUPERFACT) administered for 7 days and menstruation started and In second or third day of next cycle the dose of agonist decrease to half of previous dose. Then gonadotropin (Gonal-f ) administered. After 6 days vaginal sonography done frequently until two 18mm follicles appeared .Then HCG in 5000 unit injected IM and after36 hours oocytes punctured.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shariati Hospital

##### **Full name of responsible person**

Dr Fateme Fakhar Moghadam

##### **Street address**

Shariati Hospital, Jalal-Al-Ahmad BLV intersection  
Northern Kargar, Tehran

##### **City**

Tehran

## **Sponsors / Funding sources**

# 1

## **Sponsor**

### **Name of organization / entity**

Tehran University of Medical Sciences

### **Full name of responsible person**

Dr Fateme Fakhar Moghadam

### **Street address**

Shariati Hospital, Jalal Al Ahmad Intersection,  
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### **City**

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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**

Tehran University of Medical Sciences

## **Proportion provided by this source**

100

## **Public or private sector**

*empty*

## **Domestic or foreign origin**

*empty*

## **Category of foreign source of funding**

*empty*

## **Country of origin**

## **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

### **Contact**

#### **Name of organization / entity**

Shariati Hospital, Tehran University of Medical  
Sciences

#### **Full name of responsible person**

Dr Fateme Fakhar Moghadam

#### **Position**

General Medicine and Resident of Obstetrics and  
Gynecology

#### **Other areas of specialty/work**

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## **Person responsible for scientific**

## **inquiries**

### **Contact**

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#### **Full name of responsible person**

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#### **Position**

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#### **Other areas of specialty/work**

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## **Person responsible for updating data**

### **Contact**

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#### **Full name of responsible person**

Dr Fateme Fakhar Moghadam

#### **Position**

#### **Other areas of specialty/work**

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#### **Postal code**

#### **Phone**

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#### **Fax**

#### **Email**

#### **Web page address**

## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

*empty*

### **Study Protocol**

*empty*

### **Statistical Analysis Plan**

*empty*

### **Informed Consent Form**

*empty*

### **Clinical Study Report**

*empty*

### **Analytic Code**

*empty*

### **Data Dictionary**

*empty*