

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Ovarian response to letrozole combined with gonadotropin regimen in patient with diminished ovarian reserve candidate for IVF

#### Protocol summary

##### Study aim

to investigate the Ovarian response to letrozole combined with gonadotropin regimen in patient with decreased ovarian reserve candidate for IVF

##### Design

uncontrolled clinical trial, convenience sampling, quasi-experimental design of 69 patients with no blinding.

##### Settings and conduct

This study has investigated infertile women (age 18-42 years) visited at Infertility clinic, Mahdiyeh educational hospital, between 2017-2018 and their responses to letrozole+gonadotropin regimen is assessed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: women with poor ovarian response (POR) that at least two of the following three features (Bologna criteria) must be present: ( advanced maternal age or any other risk factor for POR; a previous POR; and an abnormal ovarian reserve test); age 18-42 yr; previous poor ovarian response (oocyte < 3) to ovarian stimulation by gonadotropin. exclusion criteria: metabolic disease (diabetes, chronic hypertension, etc) or any underlying disease ( kidney disease, liver disease, etc.); presence cancer or any malignancy; genitourinary anomalies.

##### Intervention groups

Patients received letrozole 7.5mg/day combined with gonadotropin (FSH) 225mg/day, at day 2-3 of menstrual cycle and continued for 5 days.

##### Main outcome variables

number of oocytes achieved after letrozole+gonadotropin regimen; mean endometrial thickening after letrozole+gonadotropin regimen; rate of pregnancy after letrozole+gonadotropin regimen.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140224016705N9**

Registration date: **2019-12-18, 1398/09/27**

Registration timing: **retrospective**

Last update: **2019-12-18, 1398/09/27**

Update count: **0**

##### Registration date

2019-12-18, 1398/09/27

##### Registrant information

###### Name

zahra heidar

###### Name of organization / entity

sbmu

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4461 2416

###### Email address

dr\_zheidar@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2018-03-21, 1397/01/01

##### Actual recruitment start date

2017-03-21, 1396/01/01

##### Actual recruitment end date

2018-09-23, 1397/07/01

##### Trial completion date

2018-12-22, 1397/10/01

##### Scientific title

Ovarian response to letrozole combined with gonadotropin regimen in patient with diminished ovarian reserve candidate for IVF

**Public title**

letrozole combined with gonadotropin in infertile patients with diminished ovarian reserve

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

women with poor ovarian response that at least two of the following three features(Bologna criteria) must be present: (i) advanced maternal age or any other risk factor for POR; (ii) a previousPOR; and (iii) an abnormal ovarian reserve test. age 18-42 years previous poor ovarian response(oocyte<3) to ovarian stimulation by gonadotropin.

**Exclusion criteria:**

metabolic disease (diabetes, chronic hypertension, etc) or any underlying disease ( kidney disease, liver disease, etc.) presence cancer or any malignancy genitourinary anomalies

**Age**

From **18 years** old to **42 years** old

**Gender**

Female

**Phase**

4

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **72**

Actual sample size reached: **69**

**Randomization (investigator's opinion)**

N/A

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**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**

Shahid Beheshti university of medical sciences, Arabi Ave, Yamen St, Chamran Highway, Tehran

**City**

Tehran

**Province**

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**Postal code**

1985717443

**Approval date**

2018-04-21, 1397/02/01

**Ethics committee reference number**

IR.SBMU.MSP.REC.1397.463

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

infertility

**ICD-10 code**

N97.0

**ICD-10 code description**

Female infertility associated with anovulation

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

number of oocytes achieved after letrozole+gonadotropine regimen

**Timepoint**

after ovarian puncture.

**Method of measurement**

reporting by embryology laboratory.

**2****Description**

mean endometrial thickening after letrozole+gonadotropin regimen

**Timepoint**

at injection day of HCG

**Method of measurement**

ultrasound sonography

**3****Description**

rate of pregnancy after letrozole+gonadotropin regimen

**Timepoint**

2weeks after ovarian puncture

**Method of measurement**

level of beta human chorionic gonadotropin in a sample of blood

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The patient were treated by letrozole at 7.5 mg/day (Saha pharmaceutical company) and Gonal-f at 225 mg/day (Merck pharmaceutical company), started on the 2nd-3rd day of menstrual period and

continued for 5 days. Then, once the leading follicle had reached size of 16-18mm, Ovitrelle (injectable hCG) at 250mg (Merck pharmaceutical company) was administered for patient. The patients were monitored by ultrasonography every 2 or 3 days.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mahdiyeh hospital

**Full name of responsible person**

Zahra Heidar

**Street address**

Shishegarkhaneh Ave, Fadaeiyan Eslam St, Shoosh Sq, Tehran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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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**

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**

Negar Hamzhepour

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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assistant professor

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## Person responsible for updating data

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**Full name of responsible person**  
Negar Hamzhepour  
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**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no further information

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is 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

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

all data about outcomes will be published in an article.

### When the data will become available and for how long

after publishing article.

### To whom data/document is available

there is no limitation

### Under which criteria data/document could be used

there is no criteria.

### From where data/document is obtainable

dr\_zheidar@sbmu.ac.ir

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

-

### Comments