

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison of the efficacy & effectiveness of clomiphen citrate and recombinant FSH in infertile women candidated for IUI refering to infertility clinic of vali e asr hospital

#### Protocol summary

##### Summary

The aim of this study was to compare the effectiveness and efficiency of Clomiphen Citrate and recombinant gonadotropin (r-FSH) in women candidated for IUI in infertility vale -asr r hospital This study is randomized clinical trial ,the efficacy & effectiveness of these drugs were compared and one of them as the first choice for induction ovulation in patients were selected. 30 infertile women with age lower than 40 years ;the first cycle of treatment;primary infertility;duration of infertility lower than 5years;normal uterine cavity and patent fallopian tubes;normal sperm analysis according to WHO criteri as mild male factor were selected . Women with moderate to severe endometriosis diagnosed with laparoscopy;history of prior abdominal or gynecological surgery;history of PID; allergy or contraindication for hormonal drug usage are excluded and will be randomized in tow groups (A&B)in group A,15 patients with daily usage of 50mg clomiphen citrate from 3rd to 7th day of menstrual cycle and in group B, 15 patients with75IU recombinant FSH from 4th day of menstrual cycle will be injected and sonographic monitoring will be done in 11th day.Primary outcomes are live birth rate,on going pregnancy rate.Secondary outcomes are abortion rate,multi gestation pregnancy rate and live births .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201211135181N8**  
Registration date: **2015-08-15, 1394/05/24**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-08-15, 1394/05/24

##### Registrant information

###### Name

Batool Rashidi

###### Name of organization / entity

Vali E Asr Reproductive Health Research Center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6693 9320

###### Email address

bhrashidi@tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences.

##### Expected recruitment start date

2015-01-21, 1393/11/01

##### Expected recruitment end date

2016-03-20, 1395/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficacy & effectiveness of clomiphen citrate and recombinant FSH in infertile women candidated for IUI refering to infertility clinic of vali e asr hospital

##### Public title

comparison of the efficacy & effectiveness of clomiphen citrate and recombinant FSH in infertile women candidated for IUI

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: age lower than 40 years ; the first cycle of treatment;primary infertility; duration of infertility <5years; normal uterine cavity and patent fallopian tubes approved in HSG or laparoscopy;normal sperm analysis according to WHO criterias(volume 1.5-5 ml; PH>7.2;viscosity<3;sperm concentration>20000000/ml; total sperm count>40000000;motility>50%;forward progresion>2 ; normal morphology>50%;round cell<5000000/ml;sperm aglutination<2) mild male factor . Exclusion criteria: moderate to severe endometriosis diagnosed with laparoscopy;history of prior abdominal or gynecological surgery;history of PID; history of allergy or contraindication for hormonal drug usage .

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

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

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Chancellor forResearch Tehran University of Medical Sciences

**Street address**

Medical university, Ghods street , Keshavarz BLvd.

**City**

Tehran

**Postal code**

14194

**Approval date**

2015-01-21, 1393/11/01

**Ethics committee reference number**

9011290019

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

female infertility

**ICD-10 code**

N97.0

**ICD-10 code description**

Female infertility associated with anovulation

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

clinical pregnancy

**Timepoint**

6-7 weeks after IUI(intra uterine insemination)

**Method of measurement**

sonography and geststional sac detection

**2****Description**

chemical pregnancy

**Timepoint**

2-3 weeks after IUI

**Method of measurement**

labratory test

**3****Description**

ongoing pregnancy rate

**Timepoint**

20 weeks after IUI

**Method of measurement**

SONOGRAPHY

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

Abortion

**Timepoint**

20th week of pregnancy

**Method of measurement**

follow up the patient and do sonography

**2****Description**

multi gestation pregnancy

**Timepoint**

6-7weeks after IUI

**Method of measurement**

sonography and detection several gestational sacs

### 3

**Description**

live birth rate

**Timepoint**

36-40th week of pregnancy

**Method of measurement**

follow up the patient

## Intervention groups

### 1

**Description**

in Interventional Group 1: with daily usage of 50 mg Clomiphene citrate oral tablet from 3rd to 7th day of menstrual cycle.

**Category**

Treatment - Drugs

### 2

**Description**

In intervention Group 2: Subcutaneously Daily injection of 75IU Recombinant Gonadotropine from 4th day of menstrual cycle.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Val-e-Asr Infertility Clinic

**Full name of responsible person**

Bahareh Khandzad

**Street address**

Infertility Clinic of Vali e Asr Hospital, Imam khomeini hospital, Keshavarz blvd

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Vice Chancellor for Research Tehran university of Medical Sciences

**Full name of responsible person**

Dr. Masoud Younesian

**Street address**

Tehran university of Medical Sciences, Poursina av.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Bahareh Khandzad

**Position**

Obstetrics&Gynecology resident of Tehran university of Medical Sciences

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Research Center of Infertility in Vali e Asr hospital

**Full name of responsible person**

Dr. Batool Hossein Rashidi

**Position**

Professor

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**Person responsible for updating data**

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**Full name of responsible person**

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**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*