# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Evaluation of the efficiency of clomiphene citrate plus letrozole gonadotropins for superovulation in patients undergoing intrauterine insemination: a randomized trial

### Protocol summary

**Study aim**
The aim of present study is to evaluate the efficiency of clomiphene citrate plus letrozole gonadotropins for in patients undergoing superovulation for Intrauterine Insemination (IUI).

**Design**
A randomized, non-blinded clinical trial with a parallel group design of 501 patients

**Settings and conduct**
This study is a non-blind randomized clinical trial and will be carried out on patients who will refer to Mehr medical institute and Al-Zahra hospital Rasht, Iran for infertility treatments.

**Participants/Inclusion and exclusion criteria**
IUI candidates, Inclusion criteria: Age ≤ 38 years, Basal FSH level <10, Patients without history of allergic reactions to clomiphene, Mild male factor infertility, Unexplained infertility, Anovolatory patients who have not been pregnant despite the use of ovulation induction techniques and appropriate follicles. Exclusion criteria: No response to ovulation induction, Patients with large number of follicles who cannot receive hCG

**Intervention groups**
Group A will receive clomiphene citrate (100 mg) on cycle day 3-7 (for 5 days). Group B will receive Letrozole (5 mg) on cycle day 3-7 (for 5 days). Group C will receive clomiphene citrate (50mg) plus Letrozole (2.5 mg) on cycle day 3-7 (for 5 days).

**Main outcome variables**
Clinical pregnancy

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180528039878N1**
Registration date: **2018-07-19, 1397/04/28**
Registration timing: **prospective**

Last update: **2018-07-19, 1397/04/28**
Update count: **0**

**Registration date**
2018-07-19, 1397/04/28

**Registrant information**

**Name**
Marzieh Mehrafza

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 13 3376 4270

**Email address**
dr.Mehrafza@mehrinstitute.org

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-08-23, 1397/06/01

**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**
Evaluation of the efficiency of clomiphene citrate plus letrozole gonadotropins for superovulation in patients undergoing intrauterine insemination: a randomized trial

**Public title**

Evaluation of the efficiency of clomiphene citrate plus letrozole on intrauterine insemination outcome

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age ≤ 38 years• Basal FSH level <10 Patients without history of allergic reactions to clomiphene Mild male factor infertility Unexplained infertility Anovolatory patients who have not been pregnant despite the use of ovulation induction techniques and appropriate follicles

**Exclusion criteria:**

No response to ovulation induction Patients with large number of follicles who cannot receive hCG

**Age**

To **38 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **501**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization will be used to allocate participants into the three groups (with allocation ratio of 1:1:1).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethical committee of Guilan university of medical sciences

**Street address**

Mehr Fertility Research Center, Mehr Medical Institute, Ershad St., Shahid Ansari Blvd., Rasht, Iran.

**City**

Rasht

**Province**

Guilan

**Postal code**

417861311

**Approval date**

2018-07-07, 1397/04/16

**Ethics committee reference number**

IR.GUMS.REC.1397.146

## Health conditions studied

### 1

**Description of health condition studied**

Female infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

## Primary outcomes

### 1

**Description**

Clinical pregnancy

**Timepoint**

Seven weeks after intrauterine insemination

**Method of measurement**

Observation of gestational sac on transvaginal ultrasound

## Secondary outcomes

### 1

**Description**

Number of follicles ≥ 18 mm

**Timepoint**

On hCG administration day

**Method of measurement**

By transvaginal ultrasound

### 2

**Description**

Follicular size on hCG day

**Timepoint**

On hCG administration day

**Method of measurement**

By transvaginal ultrasound

### 3

**Description**

Duration of ovarian stimulation

**Timepoint**

At the end of ovarian stimulation

**Method of measurement**

Number of days

### 4

**Description**

Endometrial thickness on hCG administration day

**Timepoint**

On hCG administration day

**Method of measurement**

By transvaginal ultrasound

**5**

**Description**
Gonadotropin dosage
**Timepoint**
At the end of ovarian stimulation
**Method of measurement**
International Units

## Intervention groups

**1**

**Description**
Intervention group: Group A will receive clomiphene citrate (100 mg, Iran Hormone) on cycle day 3-7 ( for 5 days)
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group: Group B will receive Letrozole (5 mg, SOHA, Iran) on cycle day 3-7 (for 5 days)
**Category**
Treatment - Drugs

**3**

**Description**
Intervention group: Group C will receive clomiphene citrate (100 mg, Iran Hormone) and Letrozole (5 mg, SOHA, Iran) on cycle day 3-7 (for 5 days)
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Mehr Medical institute
**Full name of responsible person**
Marzieh Mehrafza
**Street address**
Mehr Fertility Research Center, Mehr Medical Institute, Ershad St., Shahid Ansari Blvd., Rasht, Iran.
**City**
Rasht
**Province**
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**Postal code**
4178613111
**Phone**
+98 13 3376 4270
**Email**
marzieh.mehrafza@gmail.com
**Web page address**
http://www.mehrinstitute.org

**2**

**Recruitment center**
**Name of recruitment center**
Alzahra hospital
**Full name of responsible person**
Marzieh Mehrafza
**Street address**
Reproductive Health Research Center, Alzahra Hospital, Namjoo street, Rasht, Iran
**City**
Rasht
**Province**
Guilan
**Postal code**
4144654839
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+98 13 3336 9224
**Email**
marzieh.mehrafza@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mehr medical institute
**Full name of responsible person**
Marzieh Mehafza
**Street address**
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**City**
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**Province**
Guilan
**Postal code**
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**Phone**
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**Email**
marzieh.mehrafza@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mehr medical institute
**Proportion provided by this source**
70
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Other

**2**

**Sponsor**

**Name of organization / entity**
Rasht University of Medical Sciences

**Full name of responsible person**
Shadman Nemati

**Street address**
Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, ShahidSiadati St., Namjoo Ave., Rasht, Guilan, IRAN

**City**
Rasht

**Province**
Guilan

**Postal code**
6694941446

**Phone**
+98 13 3333 5820

**Email**
research@gums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Rasht University of Medical Sciences

**Proportion provided by this source**
30

**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**
Mehr medical institute

**Full name of responsible person**
Marzieh Mehrafza

**Position**
Non-academic M.D

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Reproductive Biology

**Street address**
Mehr Fertility Research Center, Mehr Medical Institute, Ershad St., Shahid Ansari Blvd., Rasht, Iran

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**Email**
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**Web page address**
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## Person responsible for scientific inquiries

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**Full name of responsible person**
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**Latest degree**
Subspecialist

**Other areas of specialty/work**
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## Person responsible for updating data

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**Position**
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**Latest degree**
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**Other areas of specialty/work**
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**Web page address**
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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 still no planning to share and publish
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be 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**
The study protocol and report will be available on completion of the trial.
**When the data will become available and for how long**
The beginning of the access period is 6 months after the publication of the study results.
**To whom data/document is available**
All people interested in this field of study
**Under which criteria data/document could be used**
Without any limitation
**From where data/document is obtainable**
az.raoufi@gmail.com
**What processes are involved for a request to access data/document**
Sending a request email
**Comments**