

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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 \leq 38 years, Basal FSH level <10 , Patients without history of allergic reactions to clomiphene, Mild male factor infertility, Unexplained infertility, Anovulatory 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

IR.GUMS.REC.1397.146

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age \leq 38 years • Basal FSH level <10 Patients without history of allergic reactions to clomiphene Mild male factor infertility Unexplained infertility Anovulatory 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

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 \geq 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

Guilan

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

Phone

+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 Mehrafza

Street address

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

City

Rasht

Province

Guilan

Postal code

4178613111

Phone

+98 13 3376 4270

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

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

City

Rasht

Province

Guilan

Postal code

4178613111

Phone

+98 13 3376 4270

Email

marzieh.mehrafza@gmail.com

Web page address<http://www.mehrinstitute.org/>**Person responsible for scientific 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

City

Rasht

Province

Guilan

Postal code

4178613111

Phone

+98 13 3376 4270

Email

marzieh.mehrafza@gmail.com

Web page address<http://www.mehrinstitute.org/>**Person responsible for updating data****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.

City

Rasht

Province

Guilan

Postal code

4178613111

Phone

+98 13 3376 4270

Email

marzieh.mehrafza@gmail.com

Web page address

<http://www.mehrinstitute.org/>

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