

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 with 75IU 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)

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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 <5 years; normal uterine cavity and patent fallopian tubes approved in HSG or laparoscopy; normal sperm analysis according to WHO criteria (volume 1.5-5 ml; PH > 7.2; viscosity < 3; sperm concentration > 20000000/ml; total sperm count > 40000000; motility > 50%; forward progression > 2 ; normal morphology > 50% ; round cell < 5000000/ml; sperm agglutination < 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 for Research 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 gestational sac detection

2

Description

chemical pregnancy

Timepoint

2-3 weeks after IUI

Method of measurement

laboratory 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

6-7 weeks 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

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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.

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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

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Person responsible for scientific inquiries

Contact

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Research Center of Infertility in Vali e Asr hospital

Full name of responsible person

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Position

Professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Researcher

Other areas of specialty/work

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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