Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Clomiphen citrate versus letrozole with gonadotropins in intrauterine insemination cycles: A prospective randomized trial

Protocol summary

Summary

Aim: This study was performed with aim to evaluate Clomiphen citrate versus letrozole with gonadotropins in intrauterine insemination cycles. Inclusion criteria: infertility and resistance to 3 cycle clomiphene therapy and candidate for intrauterine insemination. Exclusion criteria: women who didn't have consent for participation. Study population: the patients referred to Montaserieh Hospital for treatment of infertility. Sample size: 180 cases were selected. Intervention and its time: The first group received 5 mg/day letrozole on day 3-7 of menstrual cycle. The second group received 100 mg/day clomiphene in the same way as letrozole; in both groups, Human Menopausal Gonadotropin (hMG) was administered every day starting on day 6 to 8. Ovulation was triggered with urinary human chorionic gonadotropin (hCG) (5000 IU) when have two follicles of ≥16 mm. Intrauterine insemination was performed 36 hours later. Primary outcomes: Follicles size and endometrial thickness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062422900N1**
Registration date: **2016-04-22, 1395/02/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-22, 1395/02/03

Registrant information

Name

Tooran Makhdoumi

Name of organization / entity

Ghaem hospital

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2012-06-20, 1391/03/31

Expected recruitment end date

2013-06-20, 1392/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clomiphen citrate versus letrozole with gonadotropins in intrauterine insemination cycles: A prospective randomized trial

Public title

The effects of clomiphen citrate versus letrozole in treatment of infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: infertility; resistance to 3 cycle clomiphene therapy; candidate for IUI Exclusion criteria: no consent for participation

Age

No age limit

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Azadi Square, Mashhad, Khorasan Razavi,
City
Mashhad
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
87437

Health conditions studied

1

Description of health condition studied
Ovulation induction
ICD-10 code
N97.0
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
follicles size
Timepoint
the days 3, 9, 12 of the cycle
Method of measurement
Transvaginal ultrasonography

2

Description
Endometrial thickness
Timepoint
after clomiphene + HMG and letrozole + HMG
Method of measurement
By transvaginal ultrasonography

Secondary outcomes

1

Description
fertility rate
Timepoint
2 weeks after IUI
Method of measurement
by positive hCG

2

Description
fertility rate
Timepoint
2 weeks after IUI
Method of measurement
by positive hCG

Intervention groups

1

Description
In the letrozole group, letrozole 2.5 mg BID was given for 5 days from day 3 of their menstrual cycle. In addition, all the patients received a daily intramuscular HMG. The dosage was 75 IU starting on day 6 of menstrual cycle until hCG administration.
Category
Treatment - Drugs

2

Description
The patients in the clomiphene + HMG group received clomiphene citrate 50 mg twice a day (BID) for 5 days starting from day 3 of their menstrual cycle. In addition, all the patients received a daily intramuscular HMG. The dosage was 75 IU starting on day 6 of menstrual cycle until hCG administration.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Montaserieh Infertility Research Center
Full name of responsible person

Tooran Makhdoumi

Street address

Montaserieh Infertility Research Center, Montaserieh Hospital, Akhonde Khorasani Street, Mashhad, Khorasan Razavi

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Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Faculty of Mashhad University of Medical Sciences

Full name of responsible person

Mahin Naghinia

Street address

KHorasan Razavi, Mashhad, Azadi Square, Mashhad University of Medical Sciences

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Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Faculty of Mashhad 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

Ghaem Hospital

Full name of responsible person

Tooran Makhdoumi

Position

Researcher

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position

Medical Student

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