

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

A Comparative study efficacy of clomiphene citrate and letrozole on ovulation Induction in intrauterine insemination cycles Gradient technique

Protocol summary

Summary

Objectives: Comparison of efficacy of clomiphene citrate and letrozole on ovulation Induction in intrauterine insemination cycles Gradient technique. Design: Randomized, single-blind, single-center, phase II trial. Setting and conduct: For Group A, letrozole pill (dose 2.5 mg) is administered from fifth day of the menstrual cycle for 5 days. For Group B, clomiphene pill (dose 100 mg) is administered from fifth day of the menstrual cycle for 5 days. 13-14 day of menstruation, ovulation and intrauterine is evaluated. Participants including major eligibility criteria: Inclusion criteria include women who are not ovulation; exclusion criteria include irregular use of prescription drug. Intervention: For Group A, letrozole pill (dose 2.5 mg) is administered from fifth day of the menstrual cycle for 5 days. For Group B, clomiphene pill (dose 100 mg) is administered from fifth day of the menstrual cycle for 5 days. Main outcome measures variable: ovulation Induction in intrauterine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031811245N2**

Registration date: **2016-08-21, 1395/05/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-21, 1395/05/31

Registrant information

Name

Nasrin Jalilian

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative study efficacy of clomiphene citrate and letrozole on ovulation Induction in intrauterine insemination cycles Gradient technique

Public title

Efficacy of clomiphene citrate and letrozole on ovulation Induction in intrauterine insemination cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include women who are not ovulation; exclusion criteria include irregular use of prescription drug.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Building No 1, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

City

Kermanshah

Postal code**Approval date**

2015-10-20, 1394/07/28

Ethics committee reference number

KUMS.REC.1394.356

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

Anovulation

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

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

Ovulation of intrauterine

Timepoint

On the 13-14 day of menstruation

Method of measurement

According to transvaginal sonography

Secondary outcomes

empty

Intervention groups**1****Description**

Letrozole, 2.5 mg orally, once daily for 5 days

Category

Treatment - Drugs

2**Description**

clomiphene, 2.5 mg orally, once daily for 5 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Nasrin Jalilian

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Department of obstetrics and gynecology, Imam Reza Hospital, Sorkhalizheh

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Behrozeh Hamzeh

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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, Kermanshah 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
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Person responsible for updating data

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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