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)

Phone

+98 81 1427 6301

Email address

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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

Street address
Department of obstetrics and gynecology, Imam Reza Hospital, Sorkhalizheh

City
Kermanshah

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

Street address
Building No 2, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

City
Kermanshah

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

Kermanshah University of Medical sciences

Full name of responsible person

Nasrin Jalilian

Position

Specialist in obstetrics and gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Obstetrics and gynecology specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Anahita Alikhah

Position

Assistant of obstetrics and gynecology

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