

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Clomiphene citrate and Letrozole comparison in the treatment of anovulating patients

Protocol summary

Summary

Anovulation is one of the most common causes of infertility. Different drugs in various ways are prescribed for its treatment. Clomiphene citrate (Clomid) and Letrozole are categorized as ovulation induction drugs. In the present study, the effect of Clomid and Letrozole, using step up method, is compared in the treatment of infertility. In a randomized controlled clinical trial, 200 infertile patients with anovulation referred to infertility clinic of Bushehr University of Medical Sciences during 2008-2010 were studied in two equal groups. Informed written consent was obtained from all patients. For patients in each group, Letrozole or Clomid was prescribed from the third day of menstruation for five days in an increasing protocol of one, two and three tablets. Ovulation and endometrial thickness were evaluated by ultrasonography in 13th-14th day and pregnancy was confirmed by β HCG.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904154339N1**

Registration date: **2011-02-07, 1389/11/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-02-07, 1389/11/18

Registrant information

Name

Elham Rahmani

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research management center of Bushehr University of Medical Sciences

Expected recruitment start date

2009-03-10, 1387/12/20

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clomiphene citrate and Letrozole comparison in the treatment of anovulating patients

Public title

Selecting optimized method for ovulation induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile anovulating women in reproductive age Exclusion criteria: Any abnormality in thyroid and prolactin tests and structural abnormalities of uterus and tubes.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Randomized

Randomization description

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

Research management center of Bushehr University of Medical Sciences

Street address

Paradise site of Bushehr University of Medical Sciences, Rishahr street, Bahmani, Bushehr

City

Bushehr

Postal code

Approval date

2009-03-09, 1387/12/19

Ethics committee reference number

20/18/3/2407/پد

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Adequate follicle

Timepoint

The 13th - 14th day of menstruation cycle

Method of measurement

Vaginal sonography

2

Description

Endometrial thickness

Timepoint

The 13th - 14th day of menstruation cycle

Method of measurement

Vaginal sonography

3

Description

Estradiol concentration

Timepoint

The 13th - 14th day of menstruation cycle

Method of measurement

Biochemical methods for measuring estradiol titer

4

Description

Pregnancy

Timepoint

14 days after ovulation

Method of measurement

βhCG Test

5

Description

Alive fetus

Timepoint

The 7th week of pregnancy

Method of measurement

Vaginal sonography

Secondary outcomes

1

Description

Ovarian cyst

Timepoint

The 13th - 14th day of menstruation cycle

Method of measurement

Vaginal sonography

2

Description

Abnormal Uterine Bleeding

Timepoint

During menstruation cycle

Method of measurement

Patients history

Intervention groups

1

Description

Letrozole 2.5 or 5 or 7.5 mg orally according to setup protocol for 5 days since 3rd day of menstruation cycle in

first group

Category

Treatment - Drugs

2

Description

clomiphene citrate 50 or 100 or 150 mg orally according to setup protocol for 5 days since 3rd day of menstruation cycle in second group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The outpatient clinic of Bushehr University of Medical Sciences

Full name of responsible person

Dr. Elham Rahmani

Street address

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research management center of Bushehr University of Medical Sciences

Full name of responsible person

Dr. Maryam Ravani pour

Street address

Paradise site of Bushehr University of medical sciences, Rishahr street, Bahmani, Bushehr

City

Bushehr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research management center of Bushehr 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

Bushehr University of Medical Sciences, Medical Faculty

Full name of responsible person

Dr. Shahnaz Ahmadi

Position

Assistant professor of clinical obstetrics and gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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