

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effectiveness of clomiphene citrate, tamoxifen and letrozole in ovulation induction in infertility due to isolated unovulation

Protocol summary

Summary

This study was designed to compare the effectiveness of clomiphene, tamoxifen and letrozole in ovulation induction outcome: number of mature follicles, endometrial thickness, pregnancy rate, multiple pregnancy rate, live birth and miscarriage in isolated non PCOS unovulatory patient. In this prospective randomized clinical trial, 150 infertile women who had isolated nonPCOS unovulation, were randomized to 3 groups. Group A received clomiphene, 50 mg up to 150mg for 5-7days. Group B received tamoxifen 10 mg up to 30mg for 5-7 days and Group C received letrozole 2.5 mg up to 7.5mg for 5-7 days. The drugs have been increased in dose and duration to achieve mature follicle. If the patients were not responding to treatment with maximum dose for 7 days or failed to concept after six months, treatment was discontinued. Main outcome measures were number of follicles ≥ 18 mm, endometrial thickness and ovulation rate and secondary outcome measures clinical pregnancy rates, spontaneous abortions rates, multiple pregnancies, and ovarian hyperstimulation syndrome (OHSS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104096152N1**

Registration date: **2011-06-07, 1390/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-07, 1390/03/17

Registrant information

Name

Fariba Seyedoshohadaei

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 82 1328 2001

Email address

f.seyedoshohadaei@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2007-04-21, 1386/02/01

Expected recruitment end date

2009-03-20, 1387/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of clomiphene citrate, tamoxifen and letrozole in ovulation induction in infertility due to isolated unovulation

Public title

Comparison of the effectiveness of clomiphene citrate, tamoxifen and letrozole in ovulation induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women between 15 to 40 years old with infertility due to unovulation who refer to gynecologists, and they have normal semen analysis, hystrosalpingography and evidence of unovulation (include irregular menses and less than 14 mm follicle in

sonography) Exclusion criteria: Abnormal gonadotropins (LH, FSH) and prolactin, clinical finding of hyperandrogenism (including acne and hirsutism) and polycystic appearance in sonography (including ovarian enlargement and subcuticular multiple small cysts)

Age

From **15 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

Kordestan University of Medical Sciences

Street address

Besat Hospital-Keshavarz street-Sanandaj

City

Sanandaj

Postal code

Approval date

2006-06-03, 1385/03/13

Ethics committee reference number

5205/پ/14/پ

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

ovulation

Timepoint

monthly

Method of measurement

sonography

Secondary outcomes

1

Description

Live Birth

Timepoint

after delivery

Method of measurement

postpartum period

2

Description

Pregnancy

Timepoint

after missed period

Method of measurement

serum BHCG measurement

3

Description

Abortion

Timepoint

monthly in first half of pregnancy

Method of measurement

sonography

4

Description

Twin Pregnancy

Timepoint

first prenatal care

Method of measurement

sonography

Intervention groups

1

Description

Group A received clomiphene 50 mg up to 150mg for 5-7days. Treatment started with minimum dose and effect of drug monitored by sonography. Drugs have been increased in dose and duration to achieve mature follicle 18mm. If patients achieved pregnancy or were not responding to treatment with maximum dose for 7days or failed to concept after six months, treatment was discontinued.

Category

Treatment - Drugs

2**Description**

Group B received tamoxifen 10 mg up to 30mg for 5-7days. Treatment started with minimum dose and effect of drug monitored by sonography. Drugs have been increased in dose and duration to achieve mature follicle 18mm. If patients achieved pregnancy or were not responding to treatment with maximum dose for 7days or failed to concept after six months, treatment was discontinued

Category

Treatment - Drugs

3**Description**

Group C received letrozole 2.5 mg up to 7.5mg for 5-7days. Treatment started with minimum dose and effect of drug monitored by sonography. Drugs have been increased in dose and duration to achieve mature follicle 18mm. If patients achieved pregnancy or were not responding to treatment with maximum dose for 7days or failed to concept after six months, treatment was discontinued

Category

Treatment - Drugs

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

private office of Dr Fariba Seyedoshohadaei

Full name of responsible person

Fariba Seyedoshohadaei MD

Street address

Obstetric &Gynecology Department-Besat Hospital-sanandaj

City

Sanandaj

2**Recruitment center****Name of recruitment center**

Private office of Dr Farnaz Zand Vakili

Full name of responsible person

Farnaz Zandvakily MD

Street address

Obstetric &Gynecology Department-Besat Hospital-sanandaj

City

Sanandaj

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

Kordestan University of Medical Sciences and Health Services

Full name of responsible person

mr.Fardin Garibi

Street address

Kurditan University of Medial Sciences

City

Sanandaj

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kordestan University of Medical Sciences and Health Services

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**

Besat Hospital -Kurdistan University of Medical Sciences

Full name of responsible person

Fariba Seyedoshohadaei MD

Position

Assistant Professor

Other areas of specialty/work**Street address**

Obstetric &Gynecology Department-Besat Hospital-sanandaj

City

Sanandaj

Postal code**Phone**

+98 87 1328 2001

Fax**Email**

F.SEYEDOSHOHADA EI@MUK.AC.IR

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kurdistan University of Medical Sciences-Besat

Hospital

Full name of responsible person

Fariba Seyedoshohadaei MD

Position

Assistant Professor

Other areas of specialty/work

Street address

Obestetric &Gynecology Department-Besat Hospital-sanandaj

City

Sanandaj

Postal code

Phone

+98 87 1328 2001

Fax

Email

F.SEYEDOSHOHADAEI@MUK.AC.IR

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kurdistan University of Medical Sciences-Besat Hospital

Full name of responsible person

Fariba Seyedoshohadaei MD

Position

Assistant Professor

Other areas of specialty/work

Street address

Obestetric &Gynecology Department-Besat Hospital-sanandaj

City

Sanandaj

Postal code

Phone

+98 87 1328 2001

Fax

Email

F.SEYEDOSHOHADAEI@MUK.AC.IR

Web page address

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