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 folicle in

sonography) Exclusion criteria: Abnormal gondothrpins (LH, FSH) and prolactin, clinical finding of hyperandrogenism (including acne and hirsutism) and poly cystic appearance in sonography (including ovarian enlargement and subcoticular 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 measurment

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 starded 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 achived 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 starded 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 achived 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 starded 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 achived pregnanvy 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
Obestetric &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
Obestetric &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
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 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