

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of clomiphene and tamoxifen on pregnancy rate in infertile women with anovulation

Protocol summary

Summary

The aim of this study is the evaluation of the effect of clomiphene & tamoxifen in pregnancy rate. The inclusion criteria are infertile women with ovulatory dysfunction without any other causes. The exclusion criteria are: abnormal semen analysis and HSG or laparoscopy, age over 40, myoma, hyperprolactinemia, FSH over 12, hypothyroidism, hyperthyroidism, previous history of induction of ovulation, renal & liver disease and contraindication of clomiphene citrate and tamoxifen. The study population are 144 infertile women with ovulatory dysfunction who referred to infertility clinic of Alzahra hospital, after giving informed consent they randomized into two groups half of patients received tamoxifen 2 tab daily (40mg) for 5 days and the other half clomiphene 3 tab daily for 5 days from day 3-7 of menstrual cycle. Serial sonography for determination of endometrial thickness and pattern and number of dominant follicle was done. 5000 unit hcg after receiving at least one follicle ≥ 18 mm injected and then the patients compared to gather from the points of pregnancy rate and side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206131306N3**

Registration date: **2012-07-10, 1391/04/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-10, 1391/04/20

Registrant information

Name

Ziba Zahiri

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

drzibazahiri@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2007-11-11, 1386/08/20

Expected recruitment end date

2008-11-10, 1387/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of clomiphene and tamoxifen on pregnancy rate in infertile women with anovulation

Public title

Effects of clomiphene and tamoxifen on pregnancy rate in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: infertile women with ovulation disorders without other cause of infertility. Exclusion criteria: abnormal semen analysis and HSG or laparoscopy; age over 40; myoma; hyperprolactinemia; FSH over 12; hypothyroidism; hyperthyroidism; previous history of induction of ovulation; renal & liver disease and contraindication of clomiphene citrate and tamoxifen.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Guilan University of Medical Sciences

Street address

Road Tehran, Faculty of Medicine

City

rasht

Postal code**Approval date**

2007-11-11, 1386/08/20

Ethics committee reference number

443

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

Ovarian dysfunction, unspecified

ICD-10 code

E28.9

ICD-10 code description

Ovarian dysfunction, unspecified

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

Pregnancy rate

Timepoint

End of menstrual cycle

Method of measurement

Serum BhCG

Secondary outcomes**1****Description**

Abortion rate

Timepoint

End of menstrual cycle

Method of measurement

The incidence of menstrual bleeding and new

2**Description**

Multigestation rate

Timepoint

End of menstrual cycle

Method of measurement

Sonography

3**Description**

Ovarian hyperstimulation syndrome

Timepoint

End of menstrual cycle

Method of measurement

Clinical and ultrasound

4**Description**

Side effects such as headaches, dizziness, blurred vision, nausea and vomiting

Timepoint

During the treatment cycle

Method of measurement

Ask the patient

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

Prescription of 2tablet (40mg) tamoxifenfir 5 days from day 3-7 of menstrual cycle, serial sonography in day 12-16 was done for evaluation of endometrial thickness and pattern and number of mature follicles. And after reaching at least are follicle to ≥ 18 mm, injection of 5000lu HCG was done and ultimately control the incidence of pregnancy in women

Category

Treatment - Drugs

2**Description**

Prescription of 150mg clomiphen citrate for 5 days from

day 3-7 of menstrual cycle, serial sonography in day 12-16 was done for evaluation endometrial thickness and pattern and number of mature follicles, and after reaching at least one follicle to ≥ 18 mm, 5000IU HCG was injected and ultimately control the incidence of pregnancy in women

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility clinic, Alzahra hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research-Guilan University of Medical Sciences

Full name of responsible person

Dr. Abdolrasol Sobhani

Street address

Vice Chancellor for research-Guilan University of Medical Sciences I, Namjoo street

City

Rasht

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-Guilan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr.Ziba Zahiri

Position

Associated professor Guilan university of Medical Science

Other areas of specialty/work

Street address

Rasht.Namjo street.Alzahra hospital.Reproductive Health Research Center

City

Rasht

Postal code

Phone

+98 13 1322 5624

Fax

Email

drzibazahiri@gums.ac.ir drzibazahiri@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Seyedeh Fatemeh Dalil Heirati

Position

B.S.midwife

Other areas of specialty/work

Street address

Rasht.Namjo street.Alzahra hospital.Reproductive Health Research Center

City

Rasht

Postal code

Phone

+98 13 1322 5624

Fax

Email

h_fertility@gums.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

