Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 clomiphen& 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, hyperprolactinema, FSH over12, hypothyroidism, hyperthyroidism, previous history of induction of ovulation, renal & liver disease and contraindication of clomiphen citrate and tamoxifen. The study population are 144 infertile women with ovulatory dysfunction who refered to infertility clinic of Alzahra hospital, after giving informed constant they randomized into two groups half of patients received tamoxifen 2 tab daily(40mg) for 5 day and the other half clomiphen 3 tab daily for 5 day 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 ≥18mm 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; hyperprolactinema; FSH over12; hypothyroidism; hyperthyroidism; previous history of induction of ovulation; renal & liver disease and contraindication of clomiphen 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 menstural 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 ≥18mm, injection of 5000Iu 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 ≥18mm,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 l, 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

Data Dictionary	*empty*