

# 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  $\geq 18$ 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  $\geq 18$ 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  $\geq 18$ 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*

