

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Comparison of the effects of nigella sativa +pepper nigrum (nigrum Piper )with letrozole + tamoxifen in infertile woman with polycystic ovary syndrom

#### Protocol summary

##### Summary

This is a clinical trial study. The subjects in this trial are infertile women with poly cystic ovary syndrome who were referred to a gynecology clinic. Patients were selected after 12 months of intercourse without contraception is not pregnant and have normal prolactin and thyroid function test and Uterine. Tubal infertility problems caused infertility role out with hysterosalpingiography. Honeycomb view ovaries on ultrasound, amenorrhea and oligo menorrhea, too endometrial thickness are inclusion criteria of the patients in this study. Other causes of infertility in women such as endometriosis or other diseases, such as internal and surgical patients or have ovarian hyper stimulation syndrome in initial ultrasound are excluded. Patients were randomly divided into two groups. The first group, receive tamoxifen + letrozole, common poly cystic ovary syndrome treatment regimen and second group receive Nigella + black pepper with fixed doses. Tamoxifen (10 mg 2 tab QD), letrozole (2/5 mg 2 tab QD) from third to eighth day of menstrual cycle. Herbal regimen of nigella (5 cap) +black pepper (5 cap) Q8h from third to eighth day of menstrual cycle each cap dose is 550 mg. On the eighth day of the menstrual cycle vaginal ultrasound is performed. Based on the size and number of follicles medication dosage adjusted. If the size of the follicles is less than 18 mm longer continue treatment for up to five days and re-ultrasound done twelfth day cycle. If the size of follicles between 25-18 mm, and the number is less than 14, HCG injections are injected from 500 to 10,000 units. The effects of drugs and variables such as the size of the follicles and endometrial thickness and incidence of adverse events such as OHSS are examined with trans vaginal ultrasound. Pregnancy diagnosis of patients based on the results of ultrasound tests are headline  $\beta$ - HCG. The main objective of this study was to compare the effect of

letrozole+ tamoxifen with nigella + black pepper in the treatment of infertility in women with poly cystic ovarian syndrome. It is hoped we can chose a vegetarian diet or medication that is more effective and cost less.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062121653N6**

Registration date: **2017-03-18, 1395/12/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-03-18, 1395/12/28

##### Registrant information

###### Name

Athar Rasekh Jahromi

###### Name of organization / entity

Jahrom University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 5432 6602

###### Email address

a.rasekh@jums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Jahrom University of Medical Sciences

##### Expected recruitment start date

2015-09-23, 1394/07/01

##### Expected recruitment end date

2016-03-20, 1395/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effects of nigella sativa +pepper nigrum (nigrum Piper )with letrozole + tamoxifen in infertile woman with polycystic ovary syndrom

**Public title**

The effect of nigella sativa+pepper nigrum on infertility in women with PCOS

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criterion: infertile women with poly cystic ovary syndrome who are not pregnant after 12 months of unprotected intercourse. Exclusion criteria: women with other causes of infertility such as endometriosis or other surgical or internal problems who have not PCOS criteria. also,women who have evidence of ohss in primary sonography.

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**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**

Jahrom University of Medical Sciences

**Street address**

Jahrom University of Medical Sciences, Motahari St.

**City**

Jahrom

**Postal code****Approval date**

2016-04-05, 1395/01/17

**Ethics committee reference number**

IR.JUMS.REC.1394.206

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

Infertile women with polycystic ovarian syndrom

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Follicle size

**Timepoint**

Eighth and twelfth day of menstrual cycle

**Method of measurement**

Sonography

**2****Description**

number of follicles

**Timepoint**

eighth and twelfth day of menstrual cycle

**Method of measurement**

sonography

**3****Description**

endometrial thickness

**Timepoint**

eighth and twelfth day of menstrual cycle

**Method of measurement**

sonography

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

ovarian hyper stimulation syndrom

**Timepoint**

In the entire course of treatment

**Method of measurement**

Sonography

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

Intervention1: Tab tamoxifen 10mg (two tablet per day)

+Tab letrozole 2/5mg (two tablet per day) from third to eighth day of menstrual cycle

**Category**

Treatment - Drugs

**2**

**Description**

Intervention 2: cap powder of nigella 550 mg+cap powder of pepper 550 mg(po Q8h) from third to eighth day of menstrual cycle for three month

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Dr Rasekh Infertility Clinic

**Full name of responsible person**

Dr Rasekh

**Street address**

Dr Rasekh Infertility Clinic, 22 Bahman St.

**City**

Jahrom

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Dr kavus solhjo

**Street address**

Jahrom University of Medical Sciences, Motahari St.

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Jahrom 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**

**Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Dr. Rasekh Jahromi Athar

**Position**

Genicologist

**Other areas of specialty/work**

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student

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## 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*