

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 β - 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)

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+98 71 5432 6602

Email address

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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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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