Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 hysterosalpangiography. 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 eight day of menstrual cycle. Herbal regimen of nigella (5 cap) +black pepper (5 cap) Q8h from third to eight 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 ß- 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 menstural cycle
Method of measurement
Sonography

2

Description
number of follicles
Timepoint
eighth and twelfth day of menstural cycle
Method of measurement
sonography

3

Description
endometrial thickness
Timepoint
eighth and twelfth day of menstural 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.

City

Jahrom

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

Street address

Jahrom University of Medical Sciences, Motahari St.

City

Jahrom

Postal code

Phone

+98 71 5422 1040

Fax

Email

Drrasekh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Dr. Rasekh Athar

Position

Genicologist

Other areas of specialty/work

Street address

Jahrom University of Medical Sciences, Motahari St.

City

Jahrom

Postal code

Phone

+98 71 5422 1040

Fax

Email

drrasekh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

jahrom university of medical siences

Full name of responsible person

Farzaneh Najafian

Position

student

Other areas of specialty/work

Street address

jahrom,jahrom university of medical siences,Iran

City

jahrom

Postal code

-

Phone

+98 71 5437 4122

Fax

Email

najafian_f343@yahoo.com

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