Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of silymarin on serum oxidative stress markers and in vitro fertilization outcome in patients with polycystic ovarian syndrome

Protocol summary

Summary

Objectives: Despite the higher number of oocytes obtained from patients with polycystic ovarian syndrome (PCOS) and less need to gonadotropin stimulation, obtained oocytes have less potential for growth, are not able to complete meiosis, and their ability to normal fertilization and embryo formation is reduced. Oxidative stress is one of the effective factors in the incidence of some reproductive diseases such as endometriosis, PCOS, and unexplained infertility. In this study we evaluate the effect of silymarin on serum oxidative stress markers and in vitro fertilization outcome in patients with PCOS. Design: Block randomization, double blind, placebo controlled, single center, trial phase 2, including 40 women with PCOS who are candidate for in vitro fertilization. Participants including major eligibility criteria: Women with PCOS who are candidate for in vitro fertilization Intervention: Silymarin tablet, 70 mg, three times a day, orally. Placebo tablet, three times a day, orally. Main outcome measures: Paraoxonase enzyme activity, Serum concentration of malondialdehyde, Serum CRP level, Number of follicles, Endometrial thickness

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041321743N1**
Registration date: **2015-06-16, 1394/03/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-16, 1394/03/26

Registrant information

Name

Nazila Najdi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

Email address

najdin@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of silymarin on serum oxidative stress markers and in vitro fertilization outcome in patients with polycystic ovarian syndrome

Public title

Effect of Milk Thistle on relieving infertility in women with polycystic ovaries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patient satisfaction; Age between 20-35 years old; Patients with PCOS. Exclusion criteria: Patients with diabetes mellitus or hypertension; Cigarette

smoking; Using antioxidant drugs currently or in the past 3 months; Multifactorial infertility.

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Keshavarz Boulevard, Amir Abad, Tehran, Iran

City
Tehran

Postal code

Approval date
2015-03-03, 1393/12/12

Ethics committee reference number
93-12-13

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Paraoxonase enzyme activity

Timepoint
Before using silymarin and after completing usage

Method of measurement
Elisa kit

2

Description
malondialdehyde concentration

Timepoint
Before using silymarin and after completing usage

Method of measurement
Elisa kit

3

Description
C-reactive protein level

Timepoint
Before using silymarin and after completing usage

Method of measurement
Elisa kit

4

Description
number of follicles

Timepoint
After completing silymarin usage

Method of measurement
ultrasonography

5

Description
Endometrial thickness

Timepoint
After completing silymarin usage

Method of measurement
ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1. Silymarin tablet, 70 mg, three times a day, orally, made in Gol Daroo company, Iran.

Category
Treatment - Drugs

2

Description
Intervention 2. Placebo tablet, three times a day, orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Mirza Kouchak Khan hospital

Full name of responsible person
Dr Nazila Najdi

Street address
Ostad Nejatollahi street- Karim Khan boulevard

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person
Dr Masud Yunesian

Street address
Keshavarz Boulevard, Amir Abad, Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences, Vice Chancellor for Research

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
Tehran University of Medical Sciences

Full name of responsible person
Dr Nazila Najdi

Position
Obstetrician and gynecologist

Other areas of specialty/work

Street address
Mirza Kouchak Khan hospital, Ostad Nejatollahi, Karim Khan boulevard

City
Tehran

Postal code

Phone
+98 21 8889 7761

Fax

Email
najdinnazila@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Nazila Najdi

Position
Obstetrician and gynecologist

Other areas of specialty/work

Street address
Mirza Kouchak Khan hospital, Ostad Nejatollahi, Karim Khan boulevard

City
Tehran

Postal code

Phone
+98 21 8889 7761

Fax

Email
najdinnazila@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Nazila Najdi

Position
Obstetrician and gynecologist

Other areas of specialty/work

Street address
Mirza Kouchak Khan hospital, Ostad Nejatollahi, Karim Khan boulevard

City
Tehran

Postal code

Phone
+98 21 8889 7761

Fax

Email
najdinnazila@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