

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

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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

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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