

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of vitamin E and C supplements on lipid peroxidation and GSH-dependent antioxidant enzymes status in the blood of women consuming oral contraceptives

Protocol summary

Summary

Combined oral contraceptive pills (COCP) are birth prevention pills consisting estrogen and progesterone. The aim of the present prospective study was to investigate whether supplementation of vitamins C and E reduce the some side effects of COCPs. Stress oxidative in 120 healthy premenopausal (three groups) women with regular menstrual cycles, that come for family planning into health centers, would be assayed. Participants are Iranian women aged 18-40 years who use COC pills for birth control. They use COC for at least 1 year and maximum 10 years. Exclusion criteria are hormonal treatment during the last 3 months, smoking, treatment with vitamin preparations or some drugs, alcohol abuse, and the need for regular medication. In the present study we examine the effects of OC alone and with vitamin E and C supplementation on the plasma glutathione (GSH)-dependent antioxidant system and also lipid peroxidation levels in women taking the OC. Therefore, malondialdehyde (MDA) level and glutathione peroxidase (GPx) and glutathione reductase (GR) activity will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109267641N1**
Registration date: **2011-10-31, 1390/08/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-31, 1390/08/09

Registrant information

Name

Fatemeh Zal

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1230 3029

Email address

zalf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz university of medical sciences

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2011-11-22, 1390/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin E and C supplements on lipid peroxidation and GSH-dependent antioxidant enzymes status in the blood of women consuming oral contraceptives

Public title

Using antioxidants with oral contraceptives

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Iranian; age between 18-40; body mass

index (BMI) 19-25; not using other supplement drugs and vitamin during the previous 3 months; not using cigarette and alcohol; not using special drugs; not having any known disease; using contraceptive pills for at least 1 and maximum 10 years; not having breast feeding. Excluding criteria: some special disease during study; changing the pregnancy prevention way during study; exit from study or immigration.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Shiraz university of medical sciences

Street address

Zand street

City

Shiraz

Postal code

Approval date

2011-09-03, 1390/06/12

Ethics committee reference number

CT-90-5655

Health conditions studied

1

Description of health condition studied

oral contraceptive pill taking

ICD-10 code

Y42.4

ICD-10 code description

Oral contraceptives

Primary outcomes

1

Description

lipid peroxidation

Timepoint

one time and 1 month after ocp taking

Method of measurement

photometry

Secondary outcomes

1

Description

antioxidant enzymes

Timepoint

one time 1 month after ocp taking

Method of measurement

photometry

Intervention groups

1

Description

150 mg of vitamin C and 200 IU vitamin E for 4 weeks

Category

Treatment - Drugs

2

Description

no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers of Shiraz university of medical sciences

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Dr. Poost forush

Street address

Zand street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz university of medical sciences
Full name of responsible person
Dr. Fatemeh Zal
Position
PhD/ assistant professor of biochemistry
Other areas of specialty/work
Street address
Biochemistry department, Medical school, Zand street
City
Shiraz
Postal code
Phone
+98 71 1230 3029
Fax
Email
zalf@sums.ac.irfatemehzal@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz university of medical sciences
Full name of responsible person
Dr. Fatemeh Zal
Position
PhD/assistant professor of biochemistry
Other areas of specialty/work
Street address
Biochemistry department, Medical school, Zand street
City
Shiraz
Postal code
Phone
+98 71 1230 3029
Fax
Email
fatemehzal@yahoo.com
Web page address

Person responsible for updating data

Contact

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