Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz university of medical sceinces

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 sceinces
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
photometery

Secondary outcomes

1

Description
antioxidant enzymes

Timepoint
one time 1 month after ocp taking

Method of measurement
photometery

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

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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