

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Eicosapentaenoic Acid and Vitamin E Supplementation On Serum Lipid Profile, Blood Pressure, Antioxidant Status and Inflammatory Responses in Male Athletes

Protocol summary

Summary

Purpose: Investigation the effects of Eicosapentaenoic acid (EPA) supplementation, with or without vitamin E, on serum lipid profile, C-reactive protein(CRP), total antioxidant capacity, vitamin C, E and A, IL-6, and glutathione peroxidase activity in basketball players. Inclusion criteria: Healthy and athlete males with age between 17-35 year; not taking anti-oxidants 2 weeks before introducing to intervention. Exclusion criteria: Persons who treated with immunosuppressor drugs; Persons who do not want to continue intervention. Total sample was 34 from healthy, well-trained male Participants received 2 g EPA and/or 400 IU vitamin E and/or placebo depending on their groups from 2011-2012. For 6 weeks, eight subjects received an EPA supplement with vitamin E (group 1), nine subjects received an EPA supplement with vitamin E placebo (group 2), nine subjects received an EPA supplement placebo and vitamin E (group 3), and eight subjects received an EPA supplement placebo and vitamin E placebo (group 4).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211175062N6**
Registration date: **2012-11-28, 1391/09/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-28, 1391/09/08

Registrant information

Name

Reza Ghiasvand

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2742

Email address

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Recruitment status

Recruitment complete

Funding source

Food Security Research Center, Department of Community Nutrition, School of Nutrition and Food Science, University of Medical Sciences, Isfahan, Iran

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Eicosapentaenoic Acid and Vitamin E Supplementation On Serum Lipid Profile, Blood Pressure, Antioxidant Status and Inflammatory Responses in Male Athletes

Public title

Effects of Eicosapentaenoic Acid and Vitamin E Supplementation On Serum Lipid Profile and Antioxidant Status

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Healthy and athlete males with age between 17-35 year; not taking anti-oxidants 2 weeks before introducing to project
Exclusion criteria: Persons who treated with immunosuppressor drugs; Persons who do not want to continue project

Age

From **17 years** old to **35 years** old

Gender

Male

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **34**

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

Ethics Committee of Tehran University of Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

Approval date

2006-01-03, 1384/10/13

Ethics committee reference number

132/8596

Health conditions studied

1

Description of health condition studied

Serum Lipid Profile, Blood Pressure, Antioxidants Status and Inflammatory Responses

ICD-10 code

R70-R79

ICD-10 code description

Abnormal findings on examination of blood, without diagnosis

Primary outcomes

1

Description

Total Cholesterol

Timepoint

Before and 6 weeks after intervention

Method of measurement

ELISA

2

Description

LDL

Timepoint

Before and 6 weeks after intervention

Method of measurement

ELISA

3

Description

TG

Timepoint

Before and 6 weeks after intervention

Method of measurement

ELISA

4

Description

CRP

Timepoint

Before and 6 weeks after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Vitamin E, Vit C, Vit A, IL-6, Glutathion Peroxidase Activity

Timepoint

Before and 6 weeks after project

Method of measurement

Assessment of variables in venous blood level, after 2 hour activity in first day and after 6 weeks

Intervention groups

1

Description

Group 1 received an 2gr EPA supplement with 400 IU vitamin E For 6 Weeks

Category

Treatment - Drugs

2

Description

Group 2 received an 2 gr EPA supplement with 400IU vitamin E placebo For 6 Weeks

Category

Treatment - Drugs

3

Description

Group 3 received an 2gr EPA supplement placebo and 400IU vitamin E For 6 weeks

Category

Treatment - Drugs

4

Description

Group 4 received an 2 grEPA supplement placebo and 400IU vitamin E placebo For 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Food Security Research Center, Department of Community Nutrition, School of Nutrition and Food Scien

Full name of responsible person

Reza Ghiasvand

Street address

Department of Community Nutrition, Department of Nutrition and Food Science, Isfahan University of Medical Sciences, Hezar Jerib St, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Food Security Research Center, Department of Community Nutrition, School of Nutrition and Food Scien

Full name of responsible person

Reza Ghiasvand

Street address

Department of Community Nutrition, Department of Nutrition and Food Science, Isfahan University of Medical Sciences, Hezar Jerib St, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Food Security Research Center, Department of Community Nutrition, School of Nutrition and Food Scien

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

Food Security Research Center, Department of Community Nutrition

Full name of responsible person

Reza Ghiasvand

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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