

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of supplementation of L- arginine on exercise performance, body composition, Hematological indices in 35-18 year old male athletes with cardiovascular disease prevention approach

Protocol summary

Summary

The aim of this study is investigation the effect of L- arginine supplementation on performance, lipid profile, fasting blood glucose, blood sodium and potassium, body composition and blood pressure in 18-35 years male athletes. 50 male athletes ingest L-arginine (2 g/day) or placebo (2 g/day) for 45 days after randomized in a double blind manner. Some of the main inclusion criteria in our study: males 18-35 age; no consumption dietary supplement in the last two months & each of participants does not follow the intervention or catching acute or chronic disease during intervention will be excluded. Venous blood samples for determination of indicators will be taken at the beginning & end of the intervention, as well as athletic performance will be measured indirectly by the Harvard Step. Athletes during the intervention do two sessions exercise per week. They fill physical activity questionnaire and food record for each one of them at the beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121515807N1**

Registration date: **2014-03-07, 1392/12/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-07, 1392/12/16

Registrant information

Name

Naseh Pahlavani

Name of organization / entity

Student at Isfahan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-11-06, 1392/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supplementation of L- arginine on exercise performance, body composition, Hematological indices in 35-18 year old male athletes with cardiovascular disease prevention approach

Public title

Effect of sports supplements L- Arginine on athletic performance

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria included: 18-35 years old males; willing to participate in study; no smoking and alcohol; history of continuous exercise at least twice a week in a years ago; no consumption dietary supplement in the last two

months; lack of history of acute or chronic disease.
Exclusion criteria: failure to follow of intervention;
consumption of any dietary supplements in duration of
study; catching acute or chronic disease during
intervention.

Age

From **18 years** old to **35 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization include: L - arginine and placebo is
Randomly coded by someone outside the research team
and the research team know the type of supplement. The
statistical analysis is unaware of the type of intervention
and after the end of the project and the final report will
determine the type of intervention.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan Regional Bioethics Committee

Street address

Isfahan University of Medical Sciences, Hezarjarib St.,
Isfahan, Iran

City

Isfahan

Postal code

6677599-33

Approval date

2013-10-23, 1392/08/01

Ethics committee reference number

392435

2**Ethics committee****Name of ethics committee**

Isfahan University of Medical Science

Street address

Iran, Isfahan, hezarjerib Ave, Isfahan University of
Medical Science, Faculty of Nutrition and Food Science

City

Isfahan

Postal code

12345

Approval date

2013-08-20, 1392/05/29

Ethics committee reference number

392435

Health conditions studied**1****Description of health condition studied**

Prevention of cardiovascular disease risk and improve
exercise performance in healthy subjects

ICD-10 code

Z00.8

ICD-10 code description

Other general examinations

Primary outcomes**1****Description**

Performance

Timepoint

Before& after 45 intervention

Method of measurement

Harvard Step Test

2**Description**

Sodium, potassium, fasting blood glucose and lipid
profile

Timepoint

Before& after 45 intervention

Method of measurement

Blood tests

3**Description**

Blood Pressure

Timepoint

Before& after 45 intervention

Method of measurement

Mercurial pressure gauge

4**Description**

Body composition

Timepoint

Before& after 45 intervention

Method of measurement

Body composition analyser

Secondary outcomes

empty

Intervention groups

1

Description

Intervention with L- arginine supplementation (2 g per day) in 45 days in the intervention group. L-arginine pills is 1 gram & athletes take 2 tablets daily.

Category

Treatment - Drugs

2

Description

Placebo (2 g per day) in 45 days in the control group. Malto dextrin pills is 1 gram & athletes take 2 tablets daily.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sports Clubs of Isfahan University of Medical Science

Full name of responsible person

Dr.Mohamma hasan Entezari

Street address

Iran, Isfahan Hezar jerib Ave, Isfahan University of Medical Science, faculty of nutrition and food science

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Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Isfahan University of Medical Sciences

Full name of responsible person

Dr.Peyman Adibi

Street address

Isfahan University of Medical Sciences, Hezarjarib St, Isfahan 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

Research Deputy of Isfahan University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Dr.Peyman Adibi

Street address

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City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Science

Proportion provided by this source

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

3

Sponsor

Name of organization / entity

Assistance Reaserch of Isfahan University of Medical Science

Full name of responsible person

Dr.Peyman Adibi

Street address

Isfahan University of Medical Sciences, Hezarjarib St, Isfahan 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

Assistance Reaserch of Isfahan University of Medical Science

Proportion provided by this source

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*

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Student

Full name of responsible person

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Position

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Isfahan University of Medical Science

Full name of responsible person

Dr.Mohammad Hasan Entezari

Position

Specialist in nutrition and diet therapy

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Entezari@hlth.mui.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Science

Full name of responsible person

Dr.Mohammad Hasan Entezari

Position

Specialist in nutrition and diet therapy

Other areas of specialty/work**Street address**Faculty of Nutrition and Food Science, Isfahan
University of Medical Sciences, Hezarjarib St, Isfahan
Isfahan, Iran**City****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*