

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effects of carnitine and caffeine supplementation on body fat percentage, oxidative stress, lipid profile, inflammatory and atherosclerotic factors in semi-professional athletes

Protocol summary

Summary

The aim of this study is to investigate the effects of caffeine itself and with carnitine supplementation to find out their synergistic effects on weight changes, body fat percent, and also possible side effects on oxidative stress and cardiovascular health. For this purpose, 30 male soccer players will be categorized into 3 groups (n=10). First group will ingest caffeine (6 mg/kg), second group will ingest caffeine with carnitine (2 g/day), and the 3rd group will ingest placebo for 6 weeks, on their usual training days (3 days/week). To monitor each subject's food intake, 24 hour recall questionnaire will be used. During the initial visit, height, weight and Vo2max will be measured and fasting blood samples will be obtained to determine lipid profile (TG, T-C, HDL, LDL), FFA, Glucose, Creatine kinase, malondialdehyde, leptin, TNF- α and CRP levels. After 6 weeks of supplementation and usual training sessions, the above mentioned factors will be measured once again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100619411N1**

Registration date: **2014-10-15, 1393/07/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-15, 1393/07/23

Registrant information

Name

Saeed Shirali

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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shirali-s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Nutritional and Metabolic Diseases Research Center,
Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2014-11-06, 1393/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of carnitine and caffeine supplementation on body fat percentage, oxidative stress, lipid profile, inflammatory and atherosclerotic factors in semi-professional athletes

Public title

Effects of caffeine and carnitine in athletes

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Male athletes aged 20 to 30 years old; playing soccer for approximately 2 years; body mass index in the normal range; without cardiovascular disease and muscular damage
Exclusion criteria: weight

loss diet over the past month, consumption of any sport supplements 8 weeks before the study, having acute and chronic illnesses, smoking

Age

From **20 years** old to **30 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan, Ahvaz

City

Ahvaz

Postal code

6135715794

Approval date

2014-09-27, 1393/07/05

Ethics committee reference number

1393.191

Health conditions studied

1

Description of health condition studied

Athletes

ICD-10 code

Z10.3

ICD-10 code description

Routine general health check-up of sports teams

Primary outcomes

1

Description

weight changes

Timepoint

Before and after intervention

Method of measurement

Weight scale

2

Description

Body fat percentage

Timepoint

Before and after intervention

Method of measurement

Body fat Analyser

3

Description

Oxidative stress

Timepoint

Before and after intervention

Method of measurement

ELISA method

4

Description

Cardiovascular health: lipid factors(TG,TC,HDL,LDL),Fasting glucose, Free fatty acids, CRP

Timepoint

Before and after intervention

Method of measurement

ELISA and Spectrophotometry methods

Secondary outcomes

empty

Intervention groups

1

Description

Caffeine supplementation in gelatinized capsules, 6 mg/kg, 3 times per week, for 6 weeks

Category

Treatment - Drugs

2

Description

Carnitine supplementation in gelatinized capsules, 2 g/kg, 3 times per week, for 6 weeks

Category

Treatment - Drugs

3

Description

Placebo (dextrose) in gelatinized capsules, 2 g/kg, 3 times per week, for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khuzestan Province Football Association

Full name of responsible person

Damoon Ashtary

Street address

Khuzestan Province Football Association, Ahvaz, Khuzestan

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr.Seyed Ahmad Hosseini

Street address

Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Golestan

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr.Saeed Shirali

Position

Ph.D of Clinical Biochemistry

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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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