Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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

weigth 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 Spectrophotmetery 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
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Dr.Seyed Ahmad Hosseini
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Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Golestan
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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

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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