Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

The effect of L-arginine with vitamin C supplementation on nitrogen balance , body composition, VO2max, serum growth hormone, testosterone and cortisol in male body builders

Protocol summary

Study aim

The purpose of this study is to determine the effect of L-arginine with Vitamin C supplementation on Nitrogen balance, Body composition, Vo2max, Growth hormone, Testosterone and Cortisol in male body builders

Design

This is a double- blind randomized with control (placebo) clinical trial. The final sample includes 54 athletes who have been selected by convenience sampling method and are placed randomly in two groups of intervention (n=27) and control (n=27) for 6 weeks.

Settings and conduct

At The beginning and at the end of the study blood and urine samples are collected and the growth hormone, cortisol, testosterone, Vo2max, nitrogen balance and body composition are compared before and after the intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: tend to participate in the study; male gender; healthy people; age group between 18-35 years old; Exclusion criteria: Using anabolic drugs, cigarette, alcohol, any supplement during the study and before the study; cardiovascular diseases, diabetes, hypertension, acute psychiatric disorders, cold, inflammatory diseases, physical injury.

Intervention groups

The intervention group will receive daily 3 grams of L-arginine supplement 3 times a day with 500 mg vitamin C once a day for 6 weeks;The control group will receive 3 grams of L-arginine supplement 3 times a day with 500 mg of vitamin C as a placebo (starch) for 6 weeks.Each 2 groups will have a training protocol for 6 weeks, 3 sessions per week for 1 hour , based on the Cramer and Ratans protocols.

Main outcome variables

Nitrogen balance; Body composition; Vo2max; Growth Hormone; Testosterone;Cortisol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130616013678N28**
Registration date: **2019-02-14, 1397/11/25**
Registration timing: **retrospective**

Last update: **2019-02-14, 1397/11/25**
Update count: **0**

Registration date

2019-02-14, 1397/11/25

Registrant information

Name

Saeed Ghavamzadeh

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 44 1278 0803

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-01, 1397/04/10

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of L-arginine with vitamin C supplementation on nitrogen balance , body composition, VO2max, serum growth hormone, testosterone and cortisol in male body builders

Public title
The effect of L-arginine with vitamin C supplementation on nitrogen balance , body composition, VO2max, serum growth hormone, testosterone and cortisol in male body builders

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
tend to participate in the study male gender; Due to better access to male athletes rather than female athletes and tend to use supplemen healthy people age group between 18-35 years old Participants have done strength training for at least 1 year 3 times a week

Exclusion criteria:
Consumption of anabolic drugs Using cigarette and alcohol Consumption of vitamin C and L-arginine supplement before the intervention Having a certain diet Consumption of any supplement during the study People with cardiovascular diseases, pulmonary disease, diabetes, hypertension, acute psychiatric disorders, cold, inflammatory diseases, hypothyroidism Physical injury and illness during the intervention period Consumption of anti-inflammatory agents before and during the intervention Consumption of other supplements at least one month before the intervention

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

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Numbers 1 to 54 are written on the sheets and placed in a container and each patient is asked to pick a sheet randomly. At the end the ones with even numbers are placed in intervention group and the ones with odd numbers are placed in control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double blinded clinical trial that participants are randomly classified into two groups of intervention and control and none of them know in which group they are. Researchers are unaware which participants are receiving the real treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences

Street address
Orjhans street, Resalat Blvd, Urmia, Iran

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2018-03-07, 1396/12/16

Ethics committee reference number
IR.UMSU.rec.1396.412

Health conditions studied

1

Description of health condition studied
l-arginine and vitamin c supplementation

ICD-10 code

ICD-10 code description

2

Description of health condition studied
athletic performance,vo2max

ICD-10 code

ICD-10 code description

3

Description of health condition studied
nitrogen balance

ICD-10 code

ICD-10 code description

4

Description of health condition studied
Growth Hormone ,testosterone and cortisol

ICD-10 code

ICD-10 code description

5

Description of health condition studied
male body builders
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Growth Hormone
Timepoint
before and 6 weeks after trials
Method of measurement
lab test

2

Description
Testostrone Hormone
Timepoint
before and 6 weeks after trials
Method of measurement
lab test

3

Description
Cortisol Hormone
Timepoint
before and 6 weeks after trials
Method of measurement
lab test

4

Description
Nitrogen Balance
Timepoint
before and 6 weeks after trials
Method of measurement
lab test(24 hours urine collection and measurement of nitrogen urinary urea) and 24 hours recall (Determination of protein intake and calculation of nitrogen intake)

5

Description
Body composition (fat and protein percentage)
Timepoint
before and 6 weeks after trials
Method of measurement
Body composition analyzer (BIA)

6

Description
maximal oxygen consumption
Timepoint
before and 6 weeks after trials
Method of measurement
Queens step Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group will receive a 3 gram L-Arginine supplement(karen pharmaceutical company) per day with 500 mg vitamin C (Jalinous pharmaceutical company) for the period of 6 weeks.
Category
Treatment - Other

2

Description
Control group: The second group will receive a 3 gram L-Arginine supplement per day with 500 mg placebo (instead of vitamin C) for the period of 6 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
sports and health counseling of Urmia University
Full name of responsible person
Sara Sohrabi Athar
Street address
upper floor of Shahid yaghoubi Hall , Urmia University , Shahid beheshti street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr Iraj Mohebbi
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Urmia University of Medical Sciences staffs

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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
Oroumia University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr Saeed Ghavamzadeh

Position
PhD in Nutrition Science and associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
-

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available