

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effects of L-citrulline supplementation on nitric oxide and antioxidant markers after high-intensity interval exercise in humans: a randomized controlled trial

#### Protocol summary

##### Study aim

Evaluation of the effect of 12g L-citrulline supplementation before high-intensity interval exercise on the response of antioxidant markers in humans

##### Design

A double-blind randomized, placebo-controlled, and crossover design

##### Settings and conduct

After receiving participant's written and signed consent forms, their anthropometric factors such as weight, height, and body fat percentage are measured. Due to having supplementation, the researcher and participants are blinded to minimize biases. Blinding is done by the researcher assistant with coding while he knows no information about the purpose of the study and the process. Subjects consume 12g L-citrulline or placebo 1-2 hours before the start of KettleBell swing. Before exercise, first blood samples are taken from the brachial vein, after that subjects perform the protocol (16kg KettleBell swing exercise) for 12 minutes with 12 sets; then other blood samples are taken after exercise, post 10, and post 30 minutes after exercise.

##### Participants/Inclusion and exclusion criteria

The healthy and trained male students of the University of Guilan between 20 and 23 years old enter the study. Participants must be free of disease and injury, no history of surgery and musculoskeletal disorder during the last two years, and no history of ergogenic aids, supplements, and drug use in the last 6 months leading to the study.

##### Intervention groups

Intervention group: receiving L-citrulline supplementation before acute eccentric exercise ( subjects consume a solution of 12g of L-citrulline powder with water 1 to 2 hours before the start of the exercise session). Control group: receiving maltodextrin before high-intensity interval exercise ( subjects consume a solution of 12g of

maltodextrin powder with water 1 to 2 hours before the start of the exercise session).

##### Main outcome variables

Nitric Oxide; Superoxide dismutase, Catalase, Glutathione peroxidase

#### General information

##### Reason for update

Change the title

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210323050758N1**

Registration date: **2021-04-04, 1400/01/15**

Registration timing: **retrospective**

Last update: **2021-04-07, 1400/01/18**

Update count: **1**

##### Registration date

2021-04-04, 1400/01/15

##### Registrant information

###### Name

Kosar Valaei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 4428 9094

###### Email address

valaei\_kosar@msc.guilan.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-06, 1397/09/15

##### Expected recruitment end date

2018-12-23, 1397/10/02  
**Actual recruitment start date**  
2018-12-06, 1397/09/15  
**Actual recruitment end date**  
2018-12-23, 1397/10/02  
**Trial completion date**  
2018-12-23, 1397/10/02

**Scientific title**  
Effects of L-citrulline supplementation on nitric oxide and antioxidant markers after high-intensity interval exercise in humans: a randomized controlled trial

**Public title**  
Effect of L-Citrulline after high-intensity interval exercise

**Purpose**  
Basic science

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All healthy, trained male students at the University of Guilan

**Exclusion criteria:**

Being disease and injury free No history of surgery and musculoskeletal disorder during the last two years No history of ergogenic aids, supplements and drug use for in the last 6 months leading to the study

**Age**

From **20 years** old to **23 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **12**

Actual sample size reached: **9**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

By using the lottery method, we prepare 9 sheets numbered 1 to 9 that the even numbers belong to the control group and the odd numbers belong to the supplement group. Then, the lottery is done by participants. Randomization is determined by the researcher's assistant in the form of a double-blind design. Due to the crossover study, the study participants will be switched throughout to the second groups (supplement or placebo) after a washout period.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both the researcher and participants did not know if participants were receiving the supplement or a placebo in the training sessions.

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Guilan University of Medical Science

**Street address**

No. 14, Farhang Ave., Talebamoli Blvd., Amol Town

**City**

Amol

**Province**

Mazandaran

**Postal code**

4615973557

**Approval date**

2019-02-04, 1397/11/15

**Ethics committee reference number**

IR.GUMS.REC.1397.428

## Health conditions studied

### 1

**Description of health condition studied**

Evaluation of antioxidant markers

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Nitric Oxide, Superoxide dismutase, Catalase, Glutathione peroxidase

**Timepoint**

Before exercise, immediately after , post 10, and post 30 after exercise

**Method of measurement**

Blood sampling

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: participants consume a solution of 12g of l-citrulline powder supplementation with water 1 to 2 hours before the start of the exercise. Control group: participants consume a solution of 12g of maltodextrin powder with water 1 to 2 hours before the start of the exercise.

**Category**

Placebo

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Guilan University

**Full name of responsible person**

Kosar Valaei

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No. 14, Farhang Ave., Talebamoli Blvd., Amol Twon

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**Province**

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**Postal code**

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**Phone**

+98 11 4428 9094

**Email**

kosar.valaei94@gmail.com

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Mohammadreza Naghipour

**Street address**

No. 14, Farhang Ave., Talebamoli Blvd., Amol Town

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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**

Rasht 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**

Rasht University of Medical Sciences

**Full name of responsible person**

Kosar Valaei

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiology

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

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

After the study, information about the main outcome will be shared.

**When the data will become available and for how long**

6 months after publication

**To whom data/document is available**

Scientific researchers

**Under which criteria data/document could be used**

Data and results will be available for research on L-citrulline.

**From where data/document is obtainable**

Javad Mehrabani mehrabanij@guilan.ac.ir 0098 9112309074

**What processes are involved for a request to access data/document**

The data will be provided to the applicant within one month after review and approval.

**Comments**