

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effects of Short Term Citrulline malate Supplementation on Oxidative Stress Markers and Muscle damage of Trained Soccer Players

#### Protocol summary

##### Study aim

The effect of citrulline malate supplementation on oxidative stress

##### Design

Using a table of random numbers, they are divided into two groups (an intervention group and a control group). The third person is done. And the research team will not be aware of the type of supplement provided. The duration of the intervention for each group will be 7 days, during which the intervention group and the control group will be given 6 grams of citrulline malate.

##### Settings and conduct

Working in Isfahan and Isfahan University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

1-Willingness to participate in the study 2. Do not use tobacco and alcohol 3. History of playing football for three years 4. Do not use antioxidant supplements, etc. in the past month 5. Age 18 to 22 years 6. No history of any acute or chronic disease

##### Intervention groups

The intervention group received 6 grams of citrulline malate supplementation half an hour before exercise and the control group received placebo for 7 days.

##### Main outcome variables

1. There is a difference between the mean serum MDA in the control group before and after supplementation. 2- There is a difference between the mean serum TAC in the control group before and after the supplementation. 3- There is a difference between the mean serum CAT in the control group before and after the supplementation. 4- There is a difference between the mean serum SOD in the control group before and after supplementation. There is a difference between the mean serum GSH in the control group before and after the supplementation. 6- There is a difference between the mean serum UA in the control group before and after the supplementation. 7- There is a difference between the mean serum LDH in the control group before and after supplementation. 8-

There is a difference between the mean serum CK in the control group before and after the supplementation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190915044772N1**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **retrospective**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

##### Registration date

2021-02-01, 1399/11/13

##### Registrant information

##### Name

Sadegh Mirenayat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3359 8037

##### Email address

sadegh.mir1374@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-23, 1398/05/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

2019-07-23, 1398/05/01

##### Actual recruitment end date

2019-09-23, 1398/07/01

**Trial completion date**

2019-12-06, 1398/09/15

**Scientific title**

The Effects of Short Term Citrulline malate Supplementation on Oxidative Stress Markers and Muscle damage of Trained Soccer Players

**Public title**

Citrulline Malate Supplementation on Oxidative Stress Markers

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

age18-23years Professional activity history for at least 3 years Do not take antioxidant supplements Satisfaction to participate in the study

**Exclusion criteria:**

Alcohol and tobacco consumption Having a specific injury or illness Allergies or digestive problems Failure to follow the study

**Age**

From **18 years** old to **23 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **28**

Actual sample size reached: **28**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Before supplementation and after supplementation

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The study is divided into two groups (one intervention group and one control group) using a table of random numbers. Performed by a third party. And the research team will not be aware of the type of supplement provided

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The subjects were randomly divided into two groups a and b. Supplement and placebo were divided between the two groups without any apparent difference by one of my classmates who was outside the research team and was unaware of the type of supplements. One group received a supplement and the other group received a placebo

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

hezar jarib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8413647143

**Approval date**

2019-01-30, 1397/11/10

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1397.373

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

Footballer and oxidative stress

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

1 - Determining and comparing the mean of serum oxidative stress indices in the control and intervention groups, before and after supplementation

**Timepoint**

First and 7 days later

**Method of measurement**

Blood samples in the laboratory

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Citrulline malate supplement 6 g for 7 days (Karen Company)

**Category**

Rehabilitation

**2**

**Description**

Control group: placebo (malto dextrin) 6 g for 7 days (Karen Company)

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Isfahan Zobahan Cultural and Sports Club

**Full name of responsible person**

Saeid Azari

**Street address**

Shfagh Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8413613147

**Phone**

+98 31 3359 8037

**Email**

sadegh.mir1374@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amir Alavi

**Street address**

hezar jarib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8413613147

**Phone**

+98 31 3792 8000

**Email**

sadegh.mir1374@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

amir mansoor alavi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

hazar jarib

**City**

esfahan

**Province**

Isfahan

**Postal code**

8413613147

**Phone**

+98 31 3359 8037

**Email**

am.alavi@nutr.mui.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amir Alavi

**Position**

Associate professor

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+98 31 3359 8037

**Email**

sadegh.mir1374@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

sadegh.mirenayat

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

hezar jarib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8413613147

**Phone**

+98 31 3359 8037

**Email**

sadegh.mir1374@gmail.com

## Sharing plan

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

Yes - There is a plan to make this available

**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**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

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

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

Statistical data in the article

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

After publishing the article

**To whom data/document is available**

Academics

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

article

**From where data/document is obtainable**

00989133766560

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

call

**Comments**