

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of lactate and serum glucose changes with oxygen saturation, heart rate and VO<sub>2</sub>max in response to the consumption of L-carnitine and placebo during exhaustive exercise in active young men

#### Protocol summary

##### Summary

The aim of this study is to investigate the relationship between serum levels of lactate and glucose with oxygen saturation, maximal heart rate and VO<sub>2</sub>max in response to L-carnitine consumption during exhaustive exercise in young active men. Sixteen young men participate in this study. The subjects continuously add to the research and assignment is crossover in intervention giving (Supplement and Placebo); So that subsequently randomly divide into equal number groups involved Placebo and supplement (3gr L-carnitine). After the one week wash-out process, the location of the subjects of each group changed with another group. The subjects perform two sessions of the Bruce test. Serum levels of lactate, glucose, oxygen saturation (%SO<sub>2</sub>), maximal heart rate and VO<sub>2</sub>max register at before, immediately and 4min after the exhaustive exercise.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017051533979N1**

Registration date: **2017-08-26, 1396/06/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-26, 1396/06/04

##### Registrant information

###### Name

Mohsen Shabani

###### Name of organization / entity

Shahid Rajaei Teacher Training University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7784 6518

###### Email address

m.shabani1986@srttu.edu

###### Recruitment status

**Recruitment complete**

###### Funding source

Investigator

###### Expected recruitment start date

2016-11-30, 1395/09/10

###### Expected recruitment end date

2016-12-15, 1395/09/25

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparison of lactate and serum glucose changes with oxygen saturation, heart rate and VO<sub>2</sub>max in response to the consumption of L-carnitine and placebo during exhaustive exercise in active young men

###### Public title

Sport Nutrition

###### Purpose

Basic science

###### Inclusion/Exclusion criteria

Inclusion criteria: Male; Young; Physical health; Active in terms of physical activity and sports; Accommodation in a dormitory (to control nutritional conditions). Exclusion criteria: Having a history of cardiovascular and respiratory diseases; L-carnitine supplementation usage during a month before the start of the test.

###### Age

From **24 years** old to **27 years** old

**Gender**

Male

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **16**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Rajaei Teacher Training University

**Street address**

Shabanloo St, Lavizan

**City**

Tehran

**Postal code**

**Approval date**

2017-07-23, 1396/05/01

**Ethics committee reference number**

SRTTU.SSF.1396.1100

**Health conditions studied**

1

**Description of health condition studied**

Consumption of L-Carnitine during Exhaustive Exercise

**ICD-10 code**

-

**ICD-10 code description**

-

**Primary outcomes**

1

**Description**

Lactate

**Timepoint**

Before, Immediately and 4 min after the Bruce test

**Method of measurement**

By Lactometer

2

**Description**

Glucose

**Timepoint**

Before, Immediately and 4 min after the Bruce test

**Method of measurement**

By Glucometer

3

**Description**

Maximal Heart Rate (HRmax)

**Timepoint**

Immediately and 4 min after the Bruce test

**Method of measurement**

By Oximeter

4

**Description**

Oxygen Saturation (%SO<sub>2</sub>)

**Timepoint**

Before, Immediately and 4 min after the Bruce test

**Method of measurement**

By Oximeter

5

**Description**

Maximal Oxygen Consumption (VO<sub>2</sub>max)

**Timepoint**

Immediately after the Bruce test

**Method of measurement**

Calculated by Bruce test and Formula

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Giving L-carnitine supplement (3gr) along with solution of water (200gr) and a few drops lemon juice, at 90 minutes before Bruce graded exercise test on treadmill. Velocity and incline Increase in treadmill gradually and simultaneously so that initial incline is 10% and, incline increases 2% per 3 minutes until exhaustion. (in supplement group)

**Category**

Other

2

**Description**

Giving placebo that includes solution of water (200gr)

and a few drops lemon juice, at 90 minutes before Bruce graded exercise test on treadmill. Velocity and incline Increase in treadmill gradually and simultaneously so that initial incline is 10% and, incline increases 2% per 3 minutes until exhaustion. (in placebo group)

**Category**

Placebo

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

Department of Sports Science, Shahid Rajaei Teacher Training University

**Full name of responsible person**

Dr. Majid Kashef, Professor in Exercise Physiology

**Street address**

Shahid Shabanloo St, Lavizan

**City**

Tehran

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

Vice Chancellor for research of Shahid Rajaei Teacher Training University

**Full name of responsible person**

Saied Olyaei

**Street address**

Shahid Shabanloo St, Lavizan

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Shahid Rajaei Teacher Training University

**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**

Shahid Rajaei Teacher Training University

**Full name of responsible person**

Mohsen Shabani

**Position**

PhD student of Exercise Physiology

**Other areas of specialty/work****Street address**

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**Web page address**

## **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*