

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Spirulina supplementation on plasma markers of exercise-induced muscle damage, IL-6 and antioxidant capacity in Tekwando athletes: a cross-over trail.

#### Protocol summary

##### Study aim

Determining the effect of Spirulina supplementation on plasma markers of exercise-induced muscle damage, interleukin 6 and antioxidant capacity in taekwondo athletes

##### Design

This clinical trial was a double-blind, placebo-controlled crossover trial. The study had two periods separated by a 14-day washout.

##### Settings and conduct

This study is about nutritional recovery in taekwondo athletes. The study is conducted at the Taekwondo House in Tehran. The study has 2 courses and 4 days of exercise testing and blood sampling. Group 1 receives spirulina in the first period and placebo in the second period and group 2 receive placebo in the first period and spirulina in the second period. The study had two periods separated by a 14-day washout. Double-blinding is performed for the subjects and researchers. Packing, color and smell of the supplement and placebo are similar and blinding is done with the coding.

##### Participants/Inclusion and exclusion criteria

Teakwondo athletes; 3 years of experience in Taekwondo; Age from 18 to 35 years

##### Intervention groups

Receive 8 grams of spirulina sachet or 8 grams of starch flour colored with the allowed food coloring and similar essential oil for 21 days. Due to being crossover, both groups will receive a supplement and a placebo in one of the courses

##### Main outcome variables

Plasma indicators of exercise-induced muscle damage; antioxidant and inflammatory indicators

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121110011421N4**  
Registration date: **2021-07-12, 1400/04/21**  
Registration timing: **retrospective**

Last update: **2021-07-12, 1400/04/21**

Update count: **0**

##### Registration date

2021-07-12, 1400/04/21

##### Registrant information

##### Name

Kurosh Djafarian

##### Name of organization / entity

TUMS

##### Country

Iran (Islamic Republic of)

##### Phone

+98 88973901

##### Email address

[kdjafarian@tums.ac.ir](mailto:kdjafarian@tums.ac.ir)

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-09, 1398/01/20

##### Expected recruitment end date

2019-08-23, 1398/06/01

##### Actual recruitment start date

2019-05-10, 1398/02/20

##### Actual recruitment end date

2019-10-23, 1398/08/01

##### Trial completion date

2019-11-01, 1398/08/10

##### Scientific title

The effect of Spirulina supplementation on plasma markers of exercise-induced muscle damage, IL-6 and antioxidant capacity in Tekwando athletes: a cross-over trial.

**Public title**

The effect of Spirulina supplementation on plasma markers of exercise-induced muscle damage

**Purpose**

Supportive

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

Male Taekwondo Athletes Taekwondo athletes with experience of at least 3 years Age from 18 to 35 years

**Exclusion criteria:**

Tobacco and drug use in the last year Use of anti-inflammatory drugs in the last three months Follow special and unusual diets in the last three months Consumers of sports supplements in the last three months Having chronic diseases that require a person to take medicine People weighing less than 40 kg Blood donors during the month before the test People with illness or surgery in the last 3 months

**Age**

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

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **18**

Actual sample size reached: **18**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To create random sequences in this study which has two groups, the coin toss method was used. The first group includes people who first receive spirulina and then placebo, and the second group receives first placebo and then spirulina. Coin toss was performed according to the sample size and individuals were randomly assigned to one of the two groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Supplement and placebo delivered to the two groups are completely similar in appearance and the researcher will be aware of its coding at the end of the study.

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

The study is designed as a crossover. The study has two periods with a duration of 21 days. In the first period, group 1 receives spirulina and in the second period receives a placebo. Group 2 receives placebo in the first period and spirulina in the second period. The two study

periods are separated by a 14-day washout period.

**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

**Street address**

Ghods street., Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

00982181633610

**Approval date**

2017-09-13, 1396/06/22

**Ethics committee reference number**

IR.TUMS.VCR.REC.1396.3464

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

Exercise-induced muscle damage

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

Plasma levels of the lactate dehydrogenase enzyme (muscle damage Index)

**Timepoint**

Day 1 after exercise and day 22 after exercise, after a 14-day washout period, again day 1 after exercise and day 22 after exercise (4 time in total)

**Method of measurement**

Elaisa test

**2****Description**

Plasma levels of the creatine kinase enzyme (muscle damage Index)

**Timepoint**

Day 1 after exercise and day 22 after exercise, after a 14-day washout period, again day 1 after exercise and day 22 after exercise (4 time in total)

**Method of measurement**

Elaisa test

### 3

#### **Description**

Plasma levels of Interleukin 6

#### **Timepoint**

Day 1 after exercise and day 22 after exercise, after a 14-day washout period, again day 1 after exercise and day 22 after exercise (4 time in total)

#### **Method of measurement**

IL 6 kit

### 4

#### **Description**

Total antioxidant capacity (TAC)

#### **Timepoint**

Day 1 after exercise and day 22 after exercise, after a 14-day washout period, again day 1 after exercise and day 22 after exercise (4 time in total)

#### **Method of measurement**

Total antioxidant assay kit

### 5

#### **Description**

Activity of Super oxide dismutase enzyme (SOD)

#### **Timepoint**

Day 1 after exercise and day 22 after exercise, after a 14-day washout period, again day 1 after exercise and day 22 after exercise (4 time in total)

#### **Method of measurement**

Super oxide dismutase assay kit

### 6

#### **Description**

Glutathione peroxidase enzyme activity

#### **Timepoint**

Day 1 after exercise and day 22 after exercise, after a 14-day washout period, again day 1 after exercise and day 22 after exercise (4 time in total)

#### **Method of measurement**

Glutathione peroxidase assay kit

### 7

#### **Description**

Plasma level of malondialdehyde

#### **Timepoint**

Day 1 after exercise and day 22 after exercise, after a 14-day washout period, again day 1 after exercise and day 22 after exercise (4 time in total)

#### **Method of measurement**

Malondialdehyde assay kit

## **Secondary outcomes**

### 1

#### **Description**

Weight

#### **Timepoint**

Day 1 after exercise and day 22 after exercise, after a

14-day washout period, again day 1 after exercise and day 22 after exercise (4 time in total)

#### **Method of measurement**

Seca Scale

## **Intervention groups**

### 1

#### **Description**

This study has two groups. Group 1 receives spirulina in the first period of study and placebo in the second period of study. Group 2 receive placebo in the first period and spirulina in the second period. The two study periods are separated by a 14-day washout period. The duration of receiving spirulina or placebo in the first and second period is 21 days. The spirulina sachet contained 8 g of Spirulina flavored with lemon and mint (Qeshm Island Science and Technology Park by Drotat Setareh Qeshm). The placebo sachet was 8 g starch flour with the same flavor and green food coloring.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Iranian tekvando center

##### **Full name of responsible person**

Dr mohammad hozoori

##### **Street address**

Tehran Azadi complex

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1931735593

##### **Phone**

+98 21 2224 2441

##### **Email**

mhozoori@gmail.com

##### **Web page address**

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Dr mohamadali sahraeyan

##### **Street address**

Keshavarz Boulevard; Corner of Quds Street; University Central Building; Class Six

##### **City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 8898 7381

**Fax**

+98 21 8898 9664

**Email**

resdputy@tums.ac.ir

**Web page address****Grant name**

Vice Chancellor for Research, Tehran University of Medical Sciences

**Grant code / Reference number**

96-01-161-34860

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Arvin kashani

**Position**

Phd student in nutrition

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Vesk Ave., 14 street number 31

**City**

Tehran

**Province**

Tehran

**Postal code**

4545656456

**Phone**

+98 21 4436 6496

**Email**

kashani.arvin@gmail.com

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

Tehran University of Medical Sciences

**Full name of responsible person**

Kurosh djafarian

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Vesal shirazi Ave., SNSD

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 8898 4837

**Email**

kdjafarian@tums.ac.ir

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

Tehran University of Medical Sciences

**Full name of responsible person**

Arvin kashani

**Position**

Phd student in nutrition

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Vesk Ave., 14 steert number 31

**City**

Tehran

**Province**

Tehran

**Postal code**

4545656456

**Phone**

+98 21 4436 6496

**Email**

kashani.arvin@gmail.com

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

Yes - There is a plan to make this available

**Study Protocol**

No - There is not 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

According to the field of study and information received from people, all parts of it have the ability to share data

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

Access from the second half of 1400

**To whom data/document is available**

All researchers in the field of sport nutrition

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

All data obtained can be used for various analyzes

**From where data/document is obtainable**

The request should be sent to the e-mail of Dr. Kurosh Djafarian or Arvin Kashani. kdjafarian@tums.ac.ir  
kashani.arvin@gmail.com

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

After receiving the application and reviewing it by email, it will be sent to the people within 2 working weeks.

**Comments**