

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

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

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Phone

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Email

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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

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Tehran

Postal code

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Phone

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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

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Vesk Ave., 14 street number 31

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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

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

Tehran University of Medical Sciences

Full name of responsible person

Arvin kashani

Position

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Latest degree

Master

Other areas of specialty/work

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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**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