

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Dec 2023

### The effect of Tribulus terrestris supplementation on the nutritional, oxidative, inflammatory, and anti-inflammatory status and sport performance in runners

#### Protocol summary

##### Study aim

Determine the effect of Tribulus terrestris supplementation on the nutritional, oxidative, inflammatory, and anti-inflammatory status and sport performance in runners

##### Design

A double-blind controlled randomized clinical trial was designed with a sample size of 17 persons in each group. Athletes will be randomly divided into two groups using the RAS software and the placebo supplement (maltodextrin) after mating according to their VO<sub>2</sub>max and gender.

##### Settings and conduct

The present study will be conducted as a double-blind clinical trial which is aimed to determine the effect of Tribulus terrestris supplementation in runners of Tabriz stadiums.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age range of 18 to 35 years, do running workouts for at least 3 days a week (240 minutes per week) during the last 2 years, complete health (confirmed by PAR-Q questionnaire under the supervision of a doctor), the body mass index of 18.5-25, not receiving Tribulus terrestris supplement in the last three months, not doing high-intensity interval training during the last two weeks, and willingness to cooperate in the study. Exclusion criteria: musculoskeletal injuries, smoking, alcohol consumption, hormone therapy, long-term use of drugs and dietary supplements, intake of antihypertensives, diuretics and antidiabetics, pregnancy, lactation, diabetes, anemia (Hb <13g / dl), cardiovascular disease, infectious diseases, gastrointestinal problems, malignancies, and cognitive disorders.

##### Intervention groups

34 recreational runners of Tabriz stadiums; two groups of intervention (Tribulus terrestris supplementation and

physical activity) and control (maltodextrin supplementation and physical activity)

##### Main outcome variables

Nutritional status, oxidative stress, inflammatory, anti-inflammatory, and sport performance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150205020965N8**

Registration date: **2021-02-13, 1399/11/25**

Registration timing: **prospective**

Last update: **2021-02-13, 1399/11/25**

Update count: **0**

##### Registration date

2021-02-13, 1399/11/25

##### Registrant information

##### Name

Parvin Dehghan

##### Name of organization / entity

Tabriz University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3335 7580

##### Email address

dehghanp@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-20, 1399/12/02

##### Expected recruitment end date

2021-03-06, 1399/12/16  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of Tribulus terrestris supplementation on the nutritional, oxidative, inflammatory, and anti-inflammatory status and sport performance in runners

**Public title**  
The effect of Tribulus terrestris in runners

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The age range of 18 to 35 years Do running workouts for at least 3 days a week (240 minutes per week) during the last 2 years Complete health (confirmed by PAR-Q questionnaire under the supervision of a doctor) The body mass index of 18.5-25 Not receiving Tribulus terrestris supplement in the last three months Not doing high-intensity interval training during the last two weeks Willingness to cooperate in the study  
**Exclusion criteria:**  
Musculoskeletal injuries Smoking Alcohol consumption Hormone therapy Long-term use of drugs and dietary supplements Intake of antihypertensives, diuretics and antidiabetics Pregnancy Lactation Diabetes Anemia (Hb <13g / dl) Cardiovascular disease Infectious diseases Gastrointestinal problems Malignancies Cognitive disorders

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

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **34**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
After stratified random matching, individuals will be divided into two groups of intervention (Tribulus terrestris supplementation and physical activity; 17 persons) and control (maltodextrin supplementation and physical activity; 17 persons) based on gender and VO2max using RAS software.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The intervention group and the control group will consume two capsules of Tribulus terrestris (500 mg) and two capsules of maltodextrin (500 mg) each day respectively for two weeks, which is accompanied by high-intensity interval training. Supplement and placebo

will be coded with codes 1 and 2. Until the release of the patient study results, the researcher and data analyzer will not be aware of the assigned codes.

**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Tabriz University Of Medical Sciences, Nutrition Faculty, Attar Neyshabori Street, Golghash street.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

#### Approval date

2021-01-25, 1399/11/06

#### Ethics committee reference number

IR.TBZMED.REC.1399.974

## Health conditions studied

### 1

#### Description of health condition studied

runners

#### ICD-10 code

Y93.02

#### ICD-10 code description

Activity, running

## Primary outcomes

### 1

#### Description

Malondialdehyde

#### Timepoint

At baseline and two weeks after baseline

#### Method of measurement

Kit

### 2

#### Description

Total antioxidant capacity

#### Timepoint

At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 3

**Description**  
Superoxide dismutase  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 4

**Description**  
hs-CRP  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 5

**Description**  
IL-6  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 6

**Description**  
IL-10  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 7

**Description**  
Creatine kinase  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 8

**Description**  
Lactate dehydrogenase  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 9

**Description**  
Sport performance  
**Timepoint**  
At baseline and two weeks after baseline

**Method of measurement**  
questionnaire

### 10

**Description**  
Ferritin  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 11

**Description**  
Serum iron  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 12

**Description**  
Insulin  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 13

**Description**  
Glucose  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 14

**Description**  
Insulin-like Growth Factor-1  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 15

**Description**  
Adiponectin  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**  
Kit

### 16

**Description**  
PGC-1alpha expression  
**Timepoint**  
At baseline and two weeks after baseline  
**Method of measurement**

pcr

## **17**

### **Description**

Tumor necrosis factor alpha

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **18**

### **Description**

$\alpha$ 1-acid glycoprotein

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **19**

### **Description**

Myoglobin

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **20**

### **Description**

Irisin

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **21**

### **Description**

Cortisol

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **22**

### **Description**

Brain-Derived Neurotrophic Factor

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **23**

### **Description**

F2-isoprostanes

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **24**

### **Description**

8-Oxo-2'-deoxyguanosine

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **25**

### **Description**

GSH

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **26**

### **Description**

Carbonyl

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **27**

### **Description**

Nitric Oxide

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **28**

### **Description**

Neopterin

### **Timepoint**

At baseline and two weeks after baseline

### **Method of measurement**

Kit

## **Secondary outcomes**

### **1**

#### **Description**

Nutritional status (energy and macronutrients intake)

#### **Timepoint**

At baseline and two weeks after baseline

#### **Method of measurement**

3-days food intake record

### **2**

#### **Description**

Body composition

#### **Timepoint**

At baseline and two weeks after baseline

#### **Method of measurement**

(BIA, BC-418 MA)

### 3

#### **Description**

Transferrin

#### **Timepoint**

At baseline and two weeks after baseline

#### **Method of measurement**

Kit

### 4

#### **Description**

CBC

#### **Timepoint**

At baseline and two weeks after baseline

#### **Method of measurement**

Kit

### 5

#### **Description**

Serum iron

#### **Timepoint**

At baseline and two weeks after baseline

#### **Method of measurement**

Kit

### 6

#### **Description**

Sleep

#### **Timepoint**

At baseline and two weeks after baseline

#### **Method of measurement**

Questionnaire

### 7

#### **Description**

Recovery and stress

#### **Timepoint**

At baseline and two weeks after baseline

#### **Method of measurement**

Questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group: The intervention group will consume two capsules of Tribulus terrestris (500 mg) each day, which is accompanied by high-intensity interval training. One of the capsules would be taken after breakfast and the other one would be taken after lunch. To ensure the supplement consumption and follow up the recreational runners' problems, the delivery of unused capsules will be requested at the end of each week. Study subjects will be asked to report any problems too. To apply the exercise protocol, the study subjects will do high-intensity interval training for five days each week (during

two weeks).

#### **Category**

Prevention

### 2

#### **Description**

Control group: The control group will consume two capsules of maltodextrin (500 mg) each day, which is accompanied by high-intensity interval training. One of the capsules would be taken after breakfast and the other one would be taken after lunch. To ensure the supplement consumption and follow up the recreational runners' problems, the delivery of unused capsules will be requested at the end of each week. Study subjects will be asked to report any problems too. To apply the exercise protocol, the study subjects will do high-intensity interval training for five days each week (during two weeks).

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Tabriz stadiums

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

Parvin Dehghan

##### **Street address**

Faculty of Nutrition and Food Science, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

##### **City**

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East Azarbaijan

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5166614711

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+98 41 3334 0634

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dehghan.nut@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Tabriz University of Medical Sciences

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

Parvin Dehghan

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Faculty of Nutrition and Food Science, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

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dehghan.nut@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tabriz 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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Parvin Dehghan  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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dehghan.nut@gmail.com

## 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**  
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**

Reporting the results

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

After finishing the study and publishing the project articles

**To whom data/document is available**

Academic researchers

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

With permission of Project Researcher and Project Sponsor - Nutrition Research Center

**From where data/document is obtainable**

Dr. Parvin Dehghan, Faculty of Nutrition and Food Science, Tabriz University of Medical Sciences Email: Dehghan.nut@gmail.com Phone: +98 914 471 0299

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

The applicant can send an application to the responsible person by email

**Comments**