

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

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 VO₂max 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

α 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Dehghan

Street address

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
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University of Medical Sciences, Golgasht Street,
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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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