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 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
α1-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
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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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Faculty of Nutrition and Food Science, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parvin Dehghan

Position
دانشیار

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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