

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of date seed powder supplementation on the nutritional, oxidative, inflammatory and anti-inflammatory status and sport performance in runners

Protocol summary

Study aim

Determining The effect of date seed powder supplementation on nutritional, oxidative, inflammatory and anti-inflammatory status and sport performance in runners

Design

The present study will be conducted as a double-blind clinical trial with the aim of determining the effect of date seed powder supplementation indices among 36 recreational runners referring to Tabriz stadiums.

Settings and conduct

The present study will be conducted as a double-blind trial with the aim of determining the effect of date seed powder supplementation in runners referring to Tabriz stadiums.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range 18 to 35 years old; doing two exercises 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 date seed powder in the last 3 months, not doing high-intensity interval training during the last 3 months and willingness to cooperate during the study. Exclusion criteria: musculoskeletal injury; smoking; alcohol consumption; hormone therapy; long-term use of drugs; dietary supplements; intake of antihypertensives, diuretics and antidiabetics; pregnancy; lactation; diabetes; anemia (Hb <13g / dl); cardiovascular disease; infectious diseases; malignancy and cognitive disorders during the study.

Intervention groups

36 recreational runners of Tabriz stadiums; two groups of intervention (receiver of date seed powder supplement and physical activity) and control (receiver of placebo and physical activity).

Main outcome variables

Oxidative status; inflammatory status; sports performance

General information

Reason for update

No changes have been made in the protocol of the present study, and only some parameters have been added. According to the comprehensive review on registered trial, all the added parameters along with the recorded parameters were presented as a comprehensive study in this field. Unfortunately, before registering this project in the Iranian Registry of Clinical Trials due to financial constraints, some of the considered parameters were removed. Recently, due to the funding of the project via top researchers grant, researchers have re-added the deleted parameters to the project for a comprehensive study in this field.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150205020965N9**
Registration date: **2021-02-19, 1399/12/01**
Registration timing: **prospective**

Last update: **2022-06-18, 1401/03/28**

Update count: **1**

Registration date

2021-02-19, 1399/12/01

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 date seed powder supplementation on the nutritional, oxidative, inflammatory and anti-inflammatory status and sport performance in runners

Public title

The effect of date seed powder in runners

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 35 years old Doing two exercises 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 date seed powder in the last 3 months Not doing high-intensity interval training during the last 3 months Willingness to cooperate

Exclusion criteria:

Musculoskeletal injury Smoking, alcohol consumption Hormone therapy Long-term use of drugs Use of dietary supplements Pregnancy, lactation Diabetes, anemia (Hb <13g / dl), cardiovascular disease , infectious diseases, malignancy and cognitive disorders Intake of antihypertensives, diuretics and antidiabetics

Age

From 18 years old to 35 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description

Participants by using software RAS, after mating based

on sex and v20max, will be divided into two groups of 18 individual intervention (receiver of date seed powder supplement and physical activity) and control (receiver of placebo and physical activity).

Blinding (investigator's opinion)

Double blinded

Blinding description

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.1399.1011

Health conditions studied

1

Description of health condition studied

Runners

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Total antioxidant capacity

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

2

Description

Malondialdehyde

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

High-sensitivity C-reactive Protein

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

5

Description

Interleukin 10

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

6

Description

Interleukin 6

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

Insulin

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

11

Description

Glucose

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

12

Description

Insulin-like Growth Factor-1

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

13

Description

Adiponectin

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

14

Description

Tumor necrosis factor alpha

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

15

Description

Myoglobin

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

16

Description

Irisin

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

17

Description

Cortisol

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

18

Description

Brain-Derived Neurotrophic Factor

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

19

Description

F2-isoprostanes

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

20

Description

8-Oxo-2'-deoxyguanosine

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

21

Description

GSH

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

22

Description

Carbonyl protein

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

23

Description

Nitric Oxide

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

24

Description

Total oxidant status

Timepoint

At baseline and two weeks after baseline

Method of measurement

kit

25

Description

glutathione peroxidase

Timepoint

At baseline and two weeks after baseline

Method of measurement

kit

26

Description

uric acid

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

CBC (Complete blood count)

Timepoint

At baseline and two weeks after baseline

Method of measurement

Kit

4

Description

Sleep

Timepoint

At baseline and two weeks after baseline

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: during the two weeks, the intervention group will receive two packets of powder containing 13 grams of date seed powder with high-intensity interval training. One packet of pre-workout powder and one packet of post-workout powder will be added to 150 cc of lukewarm water and consumed after mixing.

Category

Prevention

2

Description

Control group: during the two weeks, the control group will receive two packets of powder containing 13 grams of wheat bran with high-intensity interval training. One packet of pre-workout powder and one packet of post-workout powder will be added to 150 cc of lukewarm water and consumed after mixing.

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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Email

dehghan.nut@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostad Rahimi

Street address

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

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Phone

+98 41 1335 2292

Email

ostadrahimi@tbzmed.ac.ir

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

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parvin Dehghan
Position
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Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

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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