# 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 v2omax, 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
**Street address**
Faculty of Nutrition and Food Science, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614711
**Phone**
+98 41 3334 0634
**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
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614711
**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**
Tabriz University Of Medical Sciences, Nutrition Faculty, Attar Neyshabori Street, Golghash street.
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Tabriz
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

**Contact**
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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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**Street address**
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**Postal code**
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**Phone**
+98 41 3334 0634
**Email**
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**