

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Production of sports drink powder based on beet extract and investigating its effect on cardio-respiratory fitness and

Protocol summary

Study aim

Determining the effect of functional bar on cardio-respiratory fitness of military forces Determining the effect of functional bar on the muscular endurance of military personnel

Design

The samples are randomly assigned to each of 2 intervention and control groups. In each group, the relevant indicators will be measured before and three hours after the intervention. The method of randomization into 2 groups will be performed by the method of random blocks of 4. Intervention group: This group consumes the designed ultra-beneficial load 3 hours before the test. Control group: This group will consume a bar without amounts of beetroot powder.

Settings and conduct

First, a list of military students who meet the entry criteria will be obtained in coordination with the administration of Imam Hossein University (AS). Then, the required samples are called at a certain time and the trial is carried out.

Participants/Inclusion and exclusion criteria

studying Students. Not having a history of cardiovascular diseases No history of bone fractures and joint diseases No smoking and drinking alcohol

Intervention groups

This group consumes the designed functional bar 3 hours before the test.

Main outcome variables

In this study, the effect of the designed formulation on 3 outcomes of the cardiorespiratory fitness index (with the test of two miles or 3200 meters running) and the endurance of the muscles of the back of the arm and chest (with the test of swimming on the hands for two minutes) and the endurance of the abdominal muscles It will be measured (with a sitting test for two minutes).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231218060454N1**

Registration date: **2023-12-21, 1402/09/30**

Registration timing: **prospective**

Last update: **2023-12-21, 1402/09/30**

Update count: **0**

Registration date

2023-12-21, 1402/09/30

Registrant information

Name

Mohammad Nejatian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8755 5516

Email address

m.nejatian@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Production of sports drink powder based on beet extract and investigating its effect on cardio-respiratory fitness and

Public title
The effect of beetroot extract on physical performance

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Studying student Not having a history of cardiovascular diseases No history of bone fractures and joint diseases No smoking and drinking alcohol
Exclusion criteria:
 All students who cannot do exercise tests at the time of study.

Age
From **18 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **31**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization into 2 groups A (intervention) and B (control) will be performed by the method of random blocks of four. In this method, using one of the randomization software, blocks of 4 including two A and two B will be produced in random order, and by repeating this process, a string of A and B will be obtained. People will be assigned to one of 2 groups A and B according to the order of entering the study according to the string produced. to hide the randomization, the closed envelope method will be used.

Blinding (investigator's opinion)
Double blinded

Blinding description
Produced bars (with and without beetroot extract) are prepared in the same packaging type; only the producer knows their content. Bars will be randomly allocated between the two groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Baqiyatullah Al-Azam Educational and Medical Center

Street address

Vanak Square, MollaSadra st, Sheykh Bahayi st

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2023-11-20, 1402/08/29

Ethics committee reference number

IR.BMSU.BAQ.REC.1402.076

Health conditions studied

1

Description of health condition studied

No applicable

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cardiorespiratory fitness

Timepoint

Before and three hours after the intervention

Method of measurement

Two mile or 3200 meter running test

2

Description

Endurance of back arm and chest muscles

Timepoint

Before and three hours after the intervention

Method of measurement

With the swimming test on the hand for two minutes

3

Description

Abdominal muscle endurance

Timepoint

Before and three hours after the intervention

Method of measurement

With the test of sitting for two minutes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group consumes the designed functional bars 3 hours before the test. Three hours after eating the bar, people will not do any physical activity. The nutritional bars of the present study without surface coating and topping will be prepared by Zarcom Company (Tehran, Iran). The weight of the resulting bar will be determined depending on the amount of nitrate in the beetroot powder (approximately 1.4 mmol/70 grams). The first step in the process of making the nutritional bar involves mixing the liquid ingredients, which include high fructose corn syrup (or honey) and peanut butter. These components are mixed in a regular mixer. The next step in the process is adding the partially dry ingredients to the liquid mixture and stirring to achieve substantial uniformity. Partial dry ingredients are sesame seeds and salt. The third step of the process in the formation of the nutritional bar is the addition of the main dry ingredients to the mixture of the second step of the process. The main dry ingredients are sugar, wheat or barley grains. These components are mixed to obtain a completely homogeneous mixture that does not require drying to form. Then the mixture is compressed in a container covered with oil paper and allowed to form a mold. Bars are cut and packed in desired shapes and sizes.

Category

Rehabilitation

2

Description

Control group: This group will take a bar with no amounts of beetroot powder. All conditions of work are similar to the intervention group, only here the formulation of the produced bar does not contain beetroot extract.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein University

Full name of responsible person

Dr. Mohammad Nejatian

Street address

Vanak Square, MollaSadra st, Sheykh Bahayi st

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Abbas Ali Imani Fouladi

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R.bmsu@yahoo.com

Web page address

<https://research.bmsu.ac.ir/portal/home/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr.Mohammad Nejatian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Food Technology and Quality Control

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr.Mohammad Nejatian
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Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

sdff

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available