

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of short-term supplementation of caffeine and beet juice with high, low dose and placebo on vasodilator indices and athletic performance in elite runners

Protocol summary

Study aim

Evaluate Acute caffeine supplementation along with beet juice effect on vasodilatory and performance factors in elite runners.

Design

Quantitative research of semi-experimental-field laboratory with targeted selection of professional runners randomly, cross-sectionally, cross-sectionally and three-blind with 3 groups, each group received all three complementary doses, so each group is considered as its own control group The realized sample size was 10 people. Randomization using dice throws both for how the first, second and third groups are selected and what dose each group receives for the first, second and third stages.

Settings and conduct

Blood sampling test and two 5000 aerobics in the Sports Medicine Center and assessment and evaluation of the National Olympic and Paralympic Academy

Participants/Inclusion and exclusion criteria

Professional male runners aged 18 to 30 with at least 3 training sessions per week. Participants were asked not to eat any diet containing nitrate or caffeine for 24 hours prior to the experiment, including sausages, processed meats, pastes, coffee, chewing gum, syrups, tea, and tobacco. For this reason, participants were given a list of all dietary sources. They were asked not to exercise heavily for 72 hours before the test.

Intervention groups

Intervention and control group 1: High dose of combined supplement (9.6 mmol nitrate in beet juice made by Sensei Pharmaceutical Company and 400 mg of caffeine made by Karen Pharmaceutical Company) which is combined with 250 cc of water. The group received all three complementary doses crossover and randomly, so each intervention group is considered as its control group.

Main outcome variables

Heart rate, systolic and diastolic blood pressure, endothelin-1 [ET-1], collagen 18, nitric oxide [NO] and nitrite levels were measured

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200707048041N1**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **retrospective**

Last update: **2020-08-23, 1399/06/02**

Update count: **0**

Registration date

2020-08-23, 1399/06/02

Registrant information

Name

Hadi Atarod

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-24, 1398/12/05

Expected recruitment end date

2020-03-14, 1398/12/24

Actual recruitment start date

2020-04-08, 1399/01/20
Actual recruitment end date
2020-06-09, 1399/03/20
Trial completion date
2020-06-19, 1399/03/30

Scientific title
The effect of short-term supplementation of caffeine and beet juice with high, low dose and placebo on vasodilator indices and athletic performance in elite runners

Public title
Evaluation of vasodilatory changes and exercise performance to caffeine-beet juice supplementation in runners

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:

No history of metabolic disease No history of smoking Intolerance to beet juice, caffeine or other natural stimulants Do not use the drug during the research period Young elite male runners Ability to perform aerobic activity

Exclusion criteria:
Having metabolic diseases such as heart disease and hypertension History of drug use History of tobacco use Having an intolerance to caffeine Having an intolerance to beet-root juice Non-runner Female gender

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

Gender
Male

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **30**
Actual sample size reached: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
First, the total sample size of 30 people consisting of members of the national endurance athletics team of the country who met the conditions in the descriptive questionnaire and had physical, health and sports conditions were determined. Then they were divided into 3 random groups so that their names were written in the same way on the same sheets and 10 of them were selected by an unrelated person for each group and divided into three groups. The names were randomly determined without replacement from the container and the order of supplementation was determined.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Subjects participating in the project, as well as the researcher who did not know the type of supplement offered to the subjects, and the collection was done only based on the number of each group and the analytical laboratory not knew the names of the individuals in each intervention group and the type of supplement they consumed

Placebo
Used

Assignment
Crossover

Other design features
Design the use of combination supplements with simultaneous random, cross-sectional, and Three-way blind intervention

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, Islamic Azad University, Science and Research Branch

Street address

Research Sciences Branch, Islamic Azad University, Hesarak St, Punak

City

Tehran

Province

Tehran

Postal code

Approval date

2020-02-21, 1398/12/02

Ethics committee reference number

IR.IAU.SRB.REC.1399.005

Health conditions studied

1

Description of health condition studied

Changes in nitrite, collagen 18, nitrous oxide, endothelin-1, systolic blood pressure, diastolic blood pressure and heart rate in professional runners due to caffeine-beet juice supplementation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart rate

Timepoint

The first and seventh days before and after two 5 km,

which lasts a total of 14 days for each stage of the intervention. This protocol is repeated in three stages and the consumption of supplements and subjects is changed.

Method of measurement

Holter

2

Description

Systolic blood pressure

Timepoint

The first and seventh days before and after two 5 km, which lasts a total of 14 days for each stage of the intervention. This protocol is repeated in three stages and the consumption of supplements and subjects is changed.

Method of measurement

Mercury barometer

3

Description

Diastolic blood pressure

Timepoint

The first and seventh days before and after two 5 km, which lasts a total of 14 days for each stage of the intervention. This protocol is repeated in three stages and the consumption of supplements and subjects is changed.

Method of measurement

Mercury barometer

4

Description

Nitrate

Timepoint

The first, second, seventh and eighth days of the intervention in the first phase of the intervention, which lasts a total of 14 days. This protocol is repeated in three stages and the consumption of supplements and subjects is changed.

Method of measurement

Blood sampling

5

Description

Nitric oxide

Timepoint

The first, second, seventh and eighth days of the intervention in the first phase of the intervention, which lasts a total of 14 days. This protocol is repeated in three stages and the consumption of supplements and subjects is changed.

Method of measurement

Blood sampling

6

Description

Collagen 18

Timepoint

The first, second, seventh and eighth days of the intervention in the first phase of the intervention, which lasts a total of 14 days. This protocol is repeated in three stages and the consumption of supplements and subjects is changed.

Method of measurement

Blood sampling

7

Description

Endothelin 1

Timepoint

The first, second, seventh and eighth days of the intervention in the first phase of the intervention, which lasts a total of 14 days. This protocol is repeated in three stages and the consumption of supplements and subjects is changed.

Method of measurement

Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention and control group 1: High dose of combined supplement (9.6 mmol nitrate in beet juice made by Sensei Pharmaceutical Company and 400 mg of caffeine made by Karen Pharmaceutical Company) which is combined with 250 cc of water. The group received all three complementary doses crossover and randomly, so each intervention group is considered as its control group.

Category

Rehabilitation

2

Description

Intervention and control group 2: Low dose of combined supplement (4.8 mmol nitrate in beet juice made by Sensai Pharmaceutical Company and 200 mg of caffeine made by Karen Pharmaceutical Company) combined with 250 cc of water. Due to the fact that all three groups received all three complementary doses crossover and randomly, each intervention group is considered as its control group.

Category

Rehabilitation

3

Description

Intervention and control group 3: placebo group Natural beet juice with 1 mmol nitrate and decaffeinated. Due to the fact that all three groups received all three complementary doses crossover and randomly, each

intervention group is considered as its control group.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Sports Medicine Center of the National Olympic Academy

Full name of responsible person

Dr.Seyed Shamseddin Taghavi

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National Olympic Academy, Enghelab Sports Complex, Seoul street

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

National Olympic Academy

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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Hadi Atarod

Position

Student

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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

There are no plans to publish. If a researcher needs the information of the participants, he / she can contact the person in charge of the article or the editor of the publication where the article is published, so that the participants can provide details if they wish.

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