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)

Phone
+98 21 2621 6193

Email address
atarodsportnutrition@gmail.com

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

IIntervention 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

Street address

National Olympic Academy، Enghelab Sports Complex، Seoul street

City

Tehran

Province

Tehran

Postal code

1995614336

Phone

+98 21 2621 6193

Fax

+98 21 2621 6195

Email

nopa.ir@gmail.com

Web page address

http://academy.olympic.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Olympic Academy

Full name of responsible person

Dr.Reza Gharakhanlu

Street address

National Olympic Academy، Enqelab Sports Complex، Seoul Street

City

Tehran

Province

Tehran

Postal code

1995614336

Phone

+98 21 2621 6188

Fax

+98 21 2621 6204

Email

nopa.ir@gmail.com

Web page address

http://academy.olympic.ir/

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

Physiology

Street address

Science and Research Branch, Islamic Azad University, University Square, Hesarak Boulevard, pounak

City

Tehran

Province

Tehran

Postal code

1477893855

Phone

+98 21 2621 6193

Fax

+98 21 2621 6195

Email

atarodsportnutrition@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Farshad Ghazalian

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Science and Research Branch، Islamic Azad University، University Square، Hesarak Boulevard،

pounak
City
Tehran
Province
Tehran
Postal code
1477893855
Phone
0098 21 44865179-82
Fax
+98 21 4486 5179
Email
phdghazalian@gmail.com
Web page address
http://human.srbiau.ac.ir/fa

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr.Farshad Ghazalian
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Science and Research Branch، Islamic Azad University، University Square، Hesarak Boulevard، pounak
City
Tehran
Province
Tehran
Postal code
1477893855
Phone
0098 21 44865179-82
Fax
+98 21 4486 5179
Email
phdghazalian@gmail.com
Web page address
http://human.srbiau.ac.ir/fa

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