Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of The Effect of Oral Potassium Nitrate Supplementation on Post-Exercise Delayed Onset Muscle Soreness (DOMS) Indices Among Sedentary Individuals Between 18 to 40 Years old: A Double-Blind Randomized Cross-Over Clinical Trial

Protocol summary

Study aim

Assessing the effect of potassium nitrate supplement (as a source of nitrate) on Post-exercise delayed onset muscle soreness (DOMS)

Design

This study is a Double-Blind Randomized Cross-Over Clinical Trial. For randomization, block randomization will be used.

Settings and conduct

This study is performed in three stages, the first stage is for the initial evaluation of demographic, anthropometric characteristics and one repetition maximum of the volunteer. Second and third stages (two weeks apart) include the measurement of variables. All stages of this study were performed in the sports medicine department of Imam Khomeini Hospital and in this study both volunteers and researchers will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes age between 18 and 40 years old; consent to enter the study; no physical or mental illness which increase the risk of disruption in the study process; sedentary lifestyle, no addiction to drugs, narcotics and tobacco, no pregnancy or breastfeeding, and no injury or pain in the biceps brachii muscle which will be evaluated. Exclusion criteria includes the use of different drugs during the week before the study, use of tonics and sports supplements during the month before the study, history of musculoskeletal injury during three months prior to participation in the study, the consumption of high nitrate containing foods before implementation of the research protocol

Intervention groups

The intervention in this study includes the use of 1000 mg of potassium nitrate (containing about 600 mg of nitrate and 400 mg of potassium) in form capsules, 20 minutes before exercise and the control section (placebo) includes the use of capsules containing stevia similar to the intervention section.

Main outcome variables

Elbow passive and active range of motion; strength of biceps brachii muscle; tenderness of biceps brachii muscle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210512051273N1**
Registration date: **2021-10-23, 1400/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-23, 1400/08/01**
Update count: **0**

Registration date

2021-10-23, 1400/08/01

Registrant information

Name

Mohammad Mahdi Tavana

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2281 8672

Email address

tavana-m@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of The Effect of Oral Potassium Nitrate Supplementation on Post-Exercise Delayed Onset Muscle Soreness (DOMS) Indices Among Sedentary Individuals Between 18 to 40 Years old: A Double-Blind Randomized Cross-Over Clinical Trial

Public title

Assessment of The Effect of Oral Potassium Nitrate Supplementation on Post-Exercise Delayed Onset Muscle Soreness Indices

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 40 years Consent to enter the study Not having physical or mental illness which increase the risk of impaired study progress Sedentary lifestyle (less than 3 days of sports activity for 30 minutes a week in the last 3 months) No addiction to drugs, narcotics and tobacco No pregnancy and breastfeeding No pain or injury in the biceps brachii muscle that will be studied

Exclusion criteria:

Taking different types of drugs during the week before the study Taking tonics and sports supplements during 1 month before History of musculoskeletal injury during the last three months Using foods containing more than 50 mg of nitrate per 100 g of food within 24 hours before the research protocol

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of volunteers will be determined by block randomization method with double, quadruple or sextet variable blocks (one group with symbol A and the other group with symbol B) and using the random number table of Random Allocation Software. Blocking and allocation sequencing for concealment will be done by someone other than the researcher (Allocation Concealment). The allocation ratio of samples will be 1:1 and the volunteers will be divided into two groups receiving potassium nitrate or placebo (Assignment).Then, based on the obtained blocks and order of allocation, one of the two types of capsules with unknown content for the researcher and the volunteer (potassium nitrate or placebo) will be given to group A for and the other capsule will be given to group B for consumption. After the wash-out period, each participant will take a capsule that they did not receive in the first round.

Blinding (investigator's opinion)

Double blinded

Blinding description

The appearance of the intervention and control group capsules is completely the same and only the contents of the capsules are different from each other. All capsules will be given to a third party before the start of the study, and the capsules will be given to the volunteers by a third party before each stage of the study, based on randomization blocks. Only the third party is aware of the contents of the capsules delivered (neither the researcher nor the volunteers will be aware) and the researcher will not be aware of the contents of the capsules given to each candidate until the final analysis of the data. The final analysis of the information will be done by the researcher.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Imam Khomeini Hospital Complex - Tehran University of Medical Sciences (Research Ethics Committee)

Street address

Deputy of Research and Technology, Imam Khomeini Hospital Complex, Gharib Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2021-09-01, 1400/06/10

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.206

Health conditions studied

1

Description of health condition studied
Post-Exercise Delayed Onset Muscle Soreness
ICD-10 code
M63
ICD-10 code description
Disorders of muscle in diseases classified elsewhere

Primary outcomes

1

Description
Biceps Brachii Muscle Tenderness
Timepoint
Before Exercise, Days 2 and 4 Post-Exercise
Method of measurement
Placing a wooden ball with a diameter of 3 cm, 3 cm above the crease of the elbow and place a sphygmomanometer on it and inflate the cuff up to 250 mm Hg and record the amount of pain on graded paper (Visual Analogue Scale)

2

Description
Strength of Biceps Brachii Muscle
Timepoint
Before Exercise, Days 2 and 4 Post-Exercise
Method of measurement
Measuring muscle force with a dynamometer

3

Description
Elbow Passive and Active Range of Motion
Timepoint
Before Exercise, Days 2 and 4 Post-Exercise
Method of measurement
Measuring angles with goniometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention in this study includes the consumption of 1000 mg of potassium nitrate (containing about 600 mg of nitrate and 400 mg of potassium) made by Qatran Shimi Tajhiz Company in the form of capsules, 20 minutes before exercise.
Category
Prevention

2

Description
Control group: The control section (placebo) includes the use of capsules containing Stevia made by Roboudian Company with the same appearance as the potassium nitrate capsule, which will be consumed similar to the intervention section (20 minutes before exercise).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor for research and technology, Tehran

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
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Mahdi Tavana

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Sport Medicine

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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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The present study has been registered as a proposal for the thesis of sports medicine residency. The dissertation resulting from this proposal including participants' data (all data), study protocol, statistical analysis and study report (including all variables) will be provided to Tehran University of Medical Sciences and Sports Medicine Department. It should be noted that after the dissertation is approved, an article containing all the items mentioned will be published in one of the journals relevant to the research topic. It should be noted that

access to detailed data that were not published in the final report or article, requires communication with the researcher in charge of the study.

When the data will become available and for how long

The present study started on 23/9/2021 and for all stages until the submission of the dissertation, a period of two years is predicted. The data obtained from this research will be presented in the form of an article after the dissertation is approved (end of 2 years) for publication. Access to the detailed data that were not published in the final report or article will be possible after the publication of the article through direct contact with the researcher in charge of the study.

To whom data/document is available

The data obtained from this research will be available to all applicants and there will be no restrictions.

Under which criteria data/document could be used

There is no restriction on the use, dissemination or processing of the data in this study, provided that correspondence is sent via email or other means to the researcher in charge of the study and the necessary permission is issued by the researcher in charge.

From where data/document is obtainable

To access the information in this study, the applicant can contact the researcher in charge of this study by e-mail or telephone.

What processes are involved for a request to access data/document

The license to use the information is issued to the applicant as soon as possible after receiving and viewing the e-mail or making a phone call, and then the requested information will immediately sent to the applicant via e-mail.

Comments