

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The acute effect of pre-anaerobic workout sodium bicarbonate intake on heart rate, heart rate variability, rating perceived exertion and anaerobic power of male athletes under hypoxic and normoxic conditions

Protocol summary

Study aim

Comparison of heart rate variability in hypoxia and normoxia training conditions and the effect of sodium bicarbonate supplement

Design

This study will be performed in four days with a rest interval of 72 hours. Subjects will first be classified into two groups of intervention (1 or 2) and control (3 or 4) based on the date of enrollment in the Excel spreadsheet. At the end of the test, Subjects will take the test as a crossover in the other group.

Settings and conduct

The test will be performed in the exercise physiology laboratory of the Faculty of Physical Education and Sports Sciences of Guilan University. This study is a double-blind study so that subjects and researchers will be unaware of supplementation in different conditions (hypoxia and normoxia).

Participants/Inclusion and exclusion criteria

Trained athlete Physical health Physical preparation to perform the anaerobic activity Cardiorespiratory health

Intervention groups

Sodium bicarbonate consumption group and anaerobic activity under normoxia (intervention) Sodium bicarbonate consumption group and anaerobic activity in hypoxia (intervention) Placebo group and anaerobic activity under normoxia (control) Placebo group and anaerobic activity in hypoxia (control)

Main outcome variables

Heart rate variability; Blood pressure; Anaerobic power of lower limb; Rate of perceived exertion; Muscle fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190720044283N3**

Registration date: **2021-10-23, 1400/08/01**

Registration timing: **retrospective**

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

Update count: **0**

Registration date

2021-10-23, 1400/08/01

Registrant information

Name

Siamand Abdollahpour

Name of organization / entity

Guilan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3369 0274

Email address

siamand.abp1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2021-10-21, 1400/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The acute effect of pre-anaerobic workout sodium bicarbonate intake on heart rate, heart rate variability,

rating perceived exertion and anaerobic power of male athletes under hypoxic and normoxic conditions	
Public title	Effect of sodium bicarbonate on anaerobic capacity under hypoxia and normoxia
Purpose	Other
Inclusion/Exclusion criteria	Inclusion criteria: Physical health and with no disease No medication and exercise supplements 6 months before the test No smoking and alcohol consumption Have regular exercise 3 days a week for the past year Age range 18 to 25 years Exclusion criteria: Inability to perform intense anaerobic activity Sensitivity to sodium bicarbonate
Age	From 18 years old to 25 years old
Gender	Male
Phase	N/A
Groups that have been masked	Participant
Sample size	Target sample size: 12
Randomization (investigator's opinion)	Randomized
Randomization description	Use the random selection method by Excel software. In this method, we first enter the names of the subjects in Excel, and then in another part, we specify the position of the desired groups in two separate sections of 6 subjects. Then in these two sections, we will execute the following code so that people are randomly placed in groups of 6 subjects. =INDEX(\$A\$3:\$A\$12,RANDBETWEEN(1,ROWS(\$A\$3:\$A\$12)),1)
Blinding (investigator's opinion)	Single blinded
Blinding description	In this study, the subjects were not aware of how the supplement or placebo was distributed. The G-physician was aware of the subjects receiving the supplement to take action if any possible allergies to the supplement occurred. Then, the physician weighed the supplement and placebo using the determined amount per weight of each subject and delivered it to the subjects for consumption in his presence by coding on each day of the test.
Placebo	Used
Assignment	Crossover
Other design features	
Secondary Ids	empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Sports Science Institute (SSRI)

Street address

Fifth Alley, Mir Emad St., Ostad Motahhari St.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2021-09-22, 1400/06/31

Ethics committee reference number

IR.SSRC.REC.1400.095

Health conditions studied

1

Description of health condition studied

Muscle fatigue during exercise activity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart rate variability

Timepoint

Before and immediately after the activity in the period of 10 minutes to 30 minutes after the activity

Method of measurement

Polar heart rate monitor (H10)

2

Description

Muscle Power

Timepoint

Before supplementation and at each point of the fatigue protocol and after completion of the activity

Method of measurement

Monark ergometer cycle and by Wingate protocol

3

Description

Systolic and diastolic blood pressure

Timepoint

Before and immediately after the activity in the period of 10 minutes to 30 minutes after the activity

Method of measurement

Beurer blood pressure monitor

4

Description

Rate of Perceived Exertion (RPE)

Timepoint

Immediately after each bout

Method of measurement

Borg scale (6-20)

5

Description

Muscle Pain

Timepoint

Immediately after each bout

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Subjects will consume 0.3 grams of sodium bicarbonate per kilogram of body weight one hour before the start of the activity. After the initial measurements and warm-up, the anaerobic activity of the Wingate will be performed by the Monark cycle ergometer and by a training mask (Phantom Athletics 001 model) in hypoxic conditions. The test process will take 9 minutes and then 30 minutes at rest (sitting) the desired variables will be monitored.

Category

Other

2

Description

Intervention group: Subjects will consume 0.3 grams of sodium bicarbonate per kilogram of body weight one hour before exercise. After the initial measurements and warm-up, the anaerobic activity of the Wingate will be performed by the Monark cycle ergometer under normoxic conditions and without a mask. The test process will take 9 minutes and then 30 minutes at rest (sitting) the desired variables will be monitored.

Category

Other

3

Description

Control group: Subjects will receive the same amount of placebo, which contains dextrose. After the initial measurements and warm-up, the anaerobic activity of the Wingate will be performed by the Monark cycle ergometer and by a training mask (Phantom Athletics 001 model) in hypoxic conditions. The test process will take 9 minutes and then 30 minutes at rest (sitting) the

desired variables will be monitored.

Category

Other

4

Description

Control group: Subjects will receive the same amount of placebo, which contains dextrose. After the initial measurements and warm-up, the anaerobic bouts of the Wingate will be performed by the Monark cycle ergometer under normoxic conditions and without a mask. The test process will take 9 minutes and then 30 minutes at rest (sitting) the desired variables will be monitored.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan university

Full name of responsible person

Siamand Abdolapour

Street address

District 5, Rasht, Gilan Province

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Guilan

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Guilan

Full name of responsible person

Seyed Ziaaldein MirHossini

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mehrabanij@guilan.ac.ir

Grant name

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

Yes

Title of funding source

University of Guilan

Proportion provided by this source

1

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

Faculty of Physical Education and Sports Sciences,
University of Guilan

Full name of responsible person

Dr. Javad Mehrabani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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Person responsible for scientific inquiries

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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Person responsible for updating data

Contact

Name of organization / entity

University of Guilan

Full name of responsible person

Siamand Abdolapour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physical Education and Sport Science

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Email

Siamand.abp1@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

After analyzing the data, only part of the data related to
the main outcome will be shared.

When the data will become available and for how

long

After approval by the journal publishing the study report

To whom data/document is available

Journal publisher of study reports

Under which criteria data/document could be used

By getting permission from the journal publish the study report

From where data/document is obtainable

Journal publisher of study reports

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

Public and private terms Journal of the study report

Comments