

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### **City**

Rasht

##### **Province**

Guilan

##### **Postal code**

4199843653

##### **Phone**

+98 13 3369 0274

##### **Email**

Siamand.abp1@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

University of Guilan

##### **Full name of responsible person**

Seyed Ziaaldein MirHossini

##### **Street address**

District 5, Rasht, Gilan Province

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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

**Street address**

8 km of Tehran road, Faculty of Physical Education  
and Sports Sciences, University of Guilan

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Faculty of Physical Education and Sports Sciences,  
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**Full name of responsible person**

Dr. Javad Mehrabani

**Position**

Assistant Professor

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

University of Guilan

**Full name of responsible person**

Siamand Abdolahpour

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physical Education and Sport Science

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**Province**

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**Postal code**

4199843653

**Phone**

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**Email**

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## 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**