

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Effect of acetazolamide on exercise performance of male physical education students in simulated altitude

#### Protocol summary

##### Study aim

Determining the effect of acetazolamide on the athletic performance of male physical education students at the simulated height

##### Design

This research project will include 14 male students of physical education at Razi University. This study has 2 groups, one group will use acetazolamide, and the other group will use a placebo. This research is one of the laboratory researches in which double-blind, randomized block studies will be performed using Random allocation software with intra-group design and mutual balance And has a clinical trial phase 3

##### Settings and conduct

This study will be performed in Kermanshah city.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Students aged 18 to 29 at Razi University; Body mass index 18 to 24. Exclusion criteria: Permanent residence at altitudes above 2000 meters; History of cognitive disorders or neurological diseases; Having a chronic illness; Smoking; History of living at altitudes of more than 2000 meters in the two months before the start of a research.

##### Intervention groups

Supplement group: acetazolamide Control group: placebo

##### Main outcome variables

Evaluation of endurance sports performance at simulated heights; Evaluation of arterial oxygen saturation at simulated altitude; Evaluate the perceived pressure at the simulated height; Heart rate assessment at simulated altitude.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170326033146N6**

Registration date: **2021-04-08, 1400/01/19**

Registration timing: **prospective**

Last update: **2021-04-08, 1400/01/19**

Update count: **0**

##### Registration date

2021-04-08, 1400/01/19

##### Registrant information

###### Name

Vahid Tadibi

###### Name of organization / entity

Razi University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3427 9265

###### Email address

vahidtadibi@razi.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-05-05, 1400/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of acetazolamide on exercise performance of male physical education students in simulated altitude

##### Public title

The effect of acetazolamide on athletic performance at

height

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Male student of Razi University 18 to 29 years old BMI: 18.5 - 29.4  
**Exclusion criteria:**  
Permanent residence at altitudes above 2000 meters  
History of cognitive disorders or neurological diseases  
Having a chronic illness Smoking History of living at altitudes of more than 2000 meters in the two months before the start of a research

**Age**  
From **18 years** old to **29 years** old

**Gender**  
Male

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **14**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Block randomization Someone other than the researchers will use the random allocation software for the allocation of the subjects by a randomized blocking method. During the process of allocation, each subject will be given a unique identification code that will be given to the main researchers together with the necessary treatment (Acetazolamide or placebo). The identification code will be used as a label to identify the group of each subject for data analysis after completion of the study. The random allocation software program can generate block randomization. The sample size and the name of the two groups (Acetazolamide and placebo) will be defined in the randomization main menu of the software. Then, the block design will be entered as equal size. Also, the format of the unique identification code will be defined as alphanumeric with fixed length. The last step is to generate the random list in which each entry in the list consists of a unique identification code and a group name.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Because this study is double-blind, the subjects and researchers will not know who take acetazolamide or placebo, and someone else will assess the results. Also, medications will be prepared in the similar capsules, and the placebo group will use lactose powder.

**Placebo**  
Used

**Assignment**  
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah Razi University

##### Street address

Tagh-e-Bostan, University St.

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

۶۷۱۴۴۱۴۹۷۱

#### Approval date

2021-02-24, 1399/12/06

#### Ethics committee reference number

IR.RAZI.REC.1399.071

## Health conditions studied

### 1

#### Description of health condition studied

Hypoxia

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Endurance training performance

#### Timepoint

The beginning of the study to assess the level of endurance function after taking acetazolamide or placebo and after hypoxia.

#### Method of measurement

The Astrand test for men is used to measure the maximum power output of the subjects.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Supplementary group: First, a cognitive function test will be performed. 48 hours later, subjects will take 2 doses of 125 mg and another dose the next morning of acetazolamide. The Astrand test will be then performed, and hypoxia will be induced immediately, and the test will be repeated. A one-week wash out period will be

considered.

### Category

Prevention

## 2

### Description

Placebo group: First, a cognitive function test will be performed. 48 hours later, subjects will take 2 doses of 125 mg and another dose the next morning. The Astrand test will be then performed, and hypoxia will be induced immediately, and the test will be repeated. A one-week wash out period will be considered.

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi university

##### Full name of responsible person

Mohammad Khazaie

##### Street address

Razi University, Shahid Ashrafi Dormitory

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

46715-65981

##### Phone

+98 83 3427 7887

##### Email

razimohammadkhazaie1995@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Razi University

##### Full name of responsible person

Farzad Veisi

##### Street address

Deputy of Research and Technology, Razi University, University St., Tagh-e-Bostan,

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6714414971

##### Phone

+98 83 3427 4515

##### Email

veysi@razi.ac.ir

##### Web page address

<https://are.razi.ac.ir/%D8%B5%D9%81%D8%AD%D9>

%87-1

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Razi University

### 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

Razi University

#### Full name of responsible person

Vahid Tadibi

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiology

#### Street address

School of Sports Sciences, Razi University, University Blvd., Taghe Bostan

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Razi University

#### Full name of responsible person

Vahid Tadibi

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Razi University  
**Full name of responsible person**  
Vahid Tadibi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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**Postal code**  
6714414971  
**Phone**

+98 83 3427 9265

**Email**  
vtadibi@yahoo.com

## 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

No more information

### 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

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

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

All Data

### When the data will become available and for how long

assess ability immediately after publication of the results

### To whom data/document is available

Researchers

### Under which criteria data/document could be used

For meta analysis

### From where data/document is obtainable

Vahid Tadibi vtadibi@yahoo.com

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

Maximum, one month after the request

### Comments