

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Acute effects of low and high doses of Taurine on physical and cognitive functions in 60-69 years old men

#### Protocol summary

##### Study aim

Determining and comparing the acute effects of low and high doses of taurine supplementation on physical and cognitive functions of men aged 60-69 years

##### Design

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 conducted as a within-subject design(crossover), counterbalanced, and double-blind study in which the researcher and the subjects do not know who will take the supplement or placebo. First, the subjects will be divided into three groups, and one hour before the tests will take one gram, six grams, or placebo, and the same thing will be repeated by changing the groups for up to 3 weeks. This research will be conducted in Sanandaj.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Living in Sanandaj Age range 60 to 69 years BMI 18 to 24 (kg /m<sup>2</sup>) Exclusion criteria: Having any chronic disease Take any supplement in the two months before the start of the study Smoking

##### Intervention groups

Supplement group: The group will consume one gram of taurine. Supplement group: The group will consume six grams of taurine. Control group: the group that will take a placebo.

##### Main outcome variables

Balance. Muscular endurance. Cardiorespiratory endurance. Cognitive function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170326033146N7**  
Registration date: **2022-01-26, 1400/11/06**  
Registration timing: **prospective**

Last update: **2022-01-26, 1400/11/06**

Update count: **0**

##### Registration date

2022-01-26, 1400/11/06

##### 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

2022-02-20, 1400/12/01

##### Expected recruitment end date

2022-03-16, 1400/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Acute effects of low and high doses of Taurine on physical and cognitive functions in 60-69 years old men

**Public title**

The effect of Taurine on cognitive and physical function

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Gender Living in Sanandaj Age range 60 to 69 years BMI 18 to 24 (kg / m<sup>2</sup>) Provide valid evidence of complete vaccination of COVID19 and at least three weeks after the second dose Having the desired level of physical fitness to perform tests based on the Physical Activity Readiness Questionnaire (Q-PAR) and physician approval

**Exclusion criteria:**

Having any chronic disease Take any supplement in the two months before the start of the study Smoking

**Age**

From **60 years** old to **69 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **15**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

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 (Different doses of taurine 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 three groups (Different doses of taurine 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 a 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 takes taurine or placebo, and someone else will assess the results. Also, in order not to detect different doses of taurine and placebo, they will be prepared in the same capsules and the placebo group will use maltodextrin 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.Razi University, Central Laboratory,Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

۶۷۱۴۴۱۴۹۷۱

**Approval date**

2022-01-12, 1400/10/22

**Ethics committee reference number**

IR.RAZI.REC.1400.088

**Health conditions studied****1****Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Balance

**Timepoint**

At the beginning of the study and after consuming one and six grams of taurine and a placebo

**Method of measurement**

Balance is measured using Timed up and go test - TUG

**2****Description**

Muscular endurance

**Timepoint**

At the beginning of the study and after consuming one and six grams of taurine and a placebo

**Method of measurement**

Muscular endurance is measured using the 30s chair stand test.

**3****Description**

Cardiorespiratory endurance

#### **Timepoint**

At the beginning of the study and after consuming one and six grams of taurine and a placebo

#### **Method of measurement**

Cardiorespiratory endurance is measured using a 6-min walk test

### **4**

#### **Description**

Cognitive function

#### **Timepoint**

At the beginning of the study and after consuming one and six grams of taurine and a placebo

#### **Method of measurement**

Cognitive function is measured using the MMSE test.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1: First, the desired tests will be performed. Subjects will be supplemented one hour before the tests. One gram of taurine supplement will be dissolved in powder in 150 ml of water. Then the desired tests are repeated. In the first week, participants will be divided into three groups of five: one gram of taurine, six grams of taurine, and a placebo. A one-week removal period will be considered. Then in the second and third weeks, the groups will move.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group 2: First, the desired tests will be performed. Subjects will be supplemented one hour before the tests. Six grams of the taurine supplement will be dissolved in powder in 150 ml of water. Then the desired tests are repeated. In the first week, participants will be divided into three groups of five: one gram of taurine, six grams of taurine, and a placebo. A one-week removal period will be considered. Then in the second and third weeks, the groups will move.

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Control group: First, the desired tests will be performed. Subjects will be supplemented one hour before the tests. 1 g of maltodextrin will be dissolved in powder in 150 ml of water. Then the desired tests are repeated. In the first week, participants will be divided into three groups of five: one gram of taurine, six grams of taurine,

and a placebo. A one-week removal period will be considered. Then in the second and third weeks, the groups will move.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Razi university

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

Reza Nasimi

##### **Street address**

Razi University, Shahid Ashrafi Dormitory

##### **City**

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## **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**

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##### **Postal code**

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##### **Phone**

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##### **Email**

veysi@razi.ac.ir

#### **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  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Razi University  
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**Position**  
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## Person responsible for updating data

### Contact

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## 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 the 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**