

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 /m²) 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

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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 / m²) 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

Full name of responsible person

Farzad Veisi

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

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

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Person responsible for updating data

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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