Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effects of a period of Ginseng Consumption on Exercise and Cognitive Performance in Sports Science Female Students during Hypoxia Condition after taking Acetazolamide

Protocol summary

Study aim

Examining the effects of ginseng on sports and cognitive performance in hypoxic conditions after taking acetazolamide

Design

This research project will include 10 female students of Razi University's physical education department. This research has 2 groups, one group will use ginseng and the other group will use placebo. This research is a type of laboratory research that will be double-blind, block-randomized using the Random Allocation softwarer, with an intra-group and counterbalanced design, and it has a clinical trial phase of 3.

Settings and conduct

Hypoxia through a hypoxia device. Place: Razi University Faculty of Sports Sciences laboratory

Participants/Inclusion and exclusion criteria

Entry requirements: Razi University students aged 18 to 29, body mass index 18.5 to 24.9, regular aerobic activity program in the 6 months before the start of the research. Conditions of non-entry: having a chronic disease, a history of cognitive disorders or neurological diseases, taking any sports supplements in the two months before the start of the research, and a history of staying at altitudes of more than 2000 meters in the two months before the start of the research.

Intervention groups

Supplemental group: the group that will take ginseng. Control group: the group that will take a placebo.

Main outcome variables

Evaluation of the time to collapse in normobaric hypoxia, evaluation of pressure perception in normobaric hypoxia, evaluation of heart rate in normobaric hypoxia, evaluation of arterial oxygen saturation in normobaric hypoxia, evaluation of cognitive function in normoxia, evaluation of cognitive function in normobaric hypoxia, evaluation of subsequent cognitive function Residual aerobic activity in normobaric hypoxia conditions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220523054967N1**
Registration date: **2022-10-03, 1401/07/11**
Registration timing: **prospective**

Last update: **2022-10-03, 1401/07/11**
Update count: **0**

Registration date

2022-10-03, 1401/07/11

Registrant information

Name

Mohana IzadiTabar

Name of organization / entity

The University of Razi

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 7605

Email address

mezady75@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-11-05, 1401/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of a period of Ginseng Consumption on Exercise and Cognitive Performance in Sports Science Female Students during Hypoxia Condition after taking Acetazolamide

Public title

The effects of ginseng on sports and cognitive performance in hypoxia conditions after taking acetazolamide

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female students in the field of physical education (third semester of bachelor's degree and above) Place of residence and education in Kermanshah city Age range of 18 to 29 years Body mass index between 18.5 and 24.9 Having general health to participate in sports activities with the doctor's approval Regular aerobic exercise program in the 6 months before the beginning of the research

Exclusion criteria:

Suffering from any chronic disease History of cognitive disorders or neurological diseases Being pregnant Excessive bleeding during menstruation History of allergies and sensitivities Consumption of any sports supplement in two months before the beginning of the research Smoking and alcohol consumption Blood donation in 2 months before the beginning of the research History of staying at altitudes of more than 2000 meters in the two months before the beginning of the research

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Someone other than researchers will use random allocation software with block randomization method to group subjects. During the grouping process, each subject will be assigned a unique identification code, which will be provided to the main researchers along with the intended intervention (ginseng or placebo). The unique identification code is used as a label to identify the group of each subject after the end of the research. The random allocation software can perform block randomization. The sample size and the names of the two groups (ginseng and placebo) are defined in the main randomization menu. Then, the block design with equal blocks is entered. Also, the formatting of the unique identification code is defined with a specific number of digits. The final step is to create a random list in which the unique identification code and group name will be specified for each number.

Blinding (investigator's opinion)

Double blinded

Blinding description

Because the study was double-blind, the subjects and the researchers did not know who would take ginseng or a placebo, and someone else would check the results. Also, in order not to distinguish the drug and the placebo, they will be prepared in the same capsules and the placebo group will use maltodextrin.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Razi University of Kermanshah

Street address

Taq Bostan, University Street

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2022-04-27, 1401/02/07

Ethics committee reference number

IR.RAZI.REC.1401.012

Health conditions studied

1

Description of health condition studied

hypoxia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Endurance sports performance

Timepoint

After taking ginseng or placebo and after applying hypoxia

Method of measurement

Astrand test for women is used to measure the maximum power of the subjects.

2

Description

Simple visual reaction time

Timepoint

At the beginning of the study to evaluate the level of cognitive function, after taking ginseng or placebo and before and after applying hypoxia

Method of measurement

Cognitive performance is assessed using a reaction time device. (RESPONSE PANEL 63035A, LAFAYETTE, INDIANA)

3

Description

Simple auditory reaction time

Timepoint

At the beginning of the study to evaluate the level of cognitive function, after taking ginseng or placebo and before and after applying hypoxia

Method of measurement

Cognitive performance is assessed using a reaction time device. (RESPONSE PANEL 63035A, LAFAYETTE, INDIANA)

4

Description

Selective visual reaction time

Timepoint

At the beginning of the study to evaluate the level of cognitive function, after taking ginseng or placebo and before and after applying hypoxia

Method of measurement

Cognitive performance is assessed using a reaction time device. (RESPONSE PANEL 63035A, LAFAYETTE, INDIANA)

5

Description

Combined reaction time

Timepoint

At the beginning of the study to evaluate the level of cognitive function, after taking ginseng or placebo and before and after applying hypoxia

Method of measurement

Cognitive performance is assessed using a reaction time device. (RESPONSE PANEL 63035A, LAFAYETTE, INDIANA)

Secondary outcomes

empty

Intervention groups

1

Description

Complementary group: Apart from the familiarization sessions and initial measurements, the subjects attend the laboratory twice and perform the reaction time test in normal conditions and simulated altitude conditions and the aerobic fitness test in simulated altitude conditions. They take ginseng for two weeks and on the last day (the day before the test) they take acetazolamide and on the day of the test they take the last dose of ginseng and acetazolamide. In other words, they consume ginseng for a period of two weeks. A one-week grace period will be considered.

Category

Prevention

2

Description

Placebo group: apart from the familiarization sessions and initial measurements, the subjects attend the laboratory twice and perform the reaction time test in normal conditions and simulated altitude conditions and the aerobic fitness test in simulated altitude conditions. They take a placebo for two weeks, and on the last day (the day before the test), they take acetazolamide, and on the day of the test, they take the last dose of placebo and acetazolamide. In other words, they take a placebo for a period of two weeks. A one-week grace period will be considered.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi University

Full name of responsible person

Mohana Izadi Tabar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Razi

Full name of responsible person

ali heirani

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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
The University of Razi

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
The University of Razi
Full name of responsible person
Vahid Tadibi
Position
Associate Professor
Latest degree
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Other areas of specialty/work
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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
There is no further 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

Total data

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

researchers

Under which criteria data/document could be used

For meta-analysis research

From where data/document is obtainable

Vahid Tadibi

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

A maximum of one month after the request

Comments