Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of Ginkgo biloba consumption on exercise and cognitive performance in male mountaineers under hypoxia condition after taking Acetazolamide

Protocol summary

Study aim

Investigating the effects of ginkgo biloba on exercise and cognitive performance in hypoxic conditions after taking acetazolamide

Design

This research project will include 12 mountaineers living in Kermanshah. This research has 2 groups, one group will use ginkgo biloba and the other group will use placebo. This research is a type of laboratory research that will be double-blind, block-randomized using Random Allocation Software, with an intra-group design and counterbalanced, and it has a phase 3 clinical trial.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Active mountaineer men aged 18 to 44 (record of climbing to altitudes higher than 4000 meters and regular climbing activity in the last year), A history of AMS in previous nights at altitudes above 3000 meters, Body mass index between 18.5 and 24.9, Having general health to participate in sports activities approved by a doctor, Regular aerobic exercise in the 6 months before the beginning of the research

Intervention groups

Ginkgo biloba group: The group that will consume ginkgo biloba. Control group: the group that will take a placebo.

Main outcome variables

1. Evaluation of the time to reach paralysis in normobaric hypoxia conditions 2. Evaluation of pressure perception, sensation scale, arousal scale, heart rate and arterial blood oxygen saturation before and after reaching collapse in normobaric hypoxia conditions 3. Evaluation of cognitive function in normoxia conditions, before and after reaching paralysis in normobaric hypoxia conditions

General information

Reason for update

Typing error, the name of the drug was given incorrectly in the intervention groups section of the placebo.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230711058744N1**
Registration date: **2023-07-20, 1402/04/29**
Registration timing: **retrospective**

Last update: **2023-12-09, 1402/09/18**
Update count: **1**

Registration date

2023-07-20, 1402/04/29

Registrant information

Name
Sara Mansouri
Name of organization / entity
The University of Razi
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-05, 1401/12/14

Expected recruitment end date

2023-04-18, 1402/01/29

Actual recruitment start date

2023-04-24, 1402/02/04

Actual recruitment end date

2023-05-28, 1402/03/07

Trial completion date

2023-06-19, 1402/03/29

Scientific title

Investigating the effect of Ginkgo biloba consumption on exercise and cognitive performance in male mountaineers under hypoxia condition after taking Acetazolamide

Public title

The effects of Ginkgo biloba on exercise and cognitive performance in hypoxic conditions after taking acetazolamide

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Active mountaineer men aged 18 to 44 years (history of climbing to altitudes higher than 4000 meters and regular climbing activity in the past one year) History of AMS in previous nights at altitudes higher than 3000 meters Body mass index between 18.5 and 24.9 Having general health to participate in sports activities approved by the doctor Regular aerobic exercise in 6 months before the beginning of the research (at least three sessions per week, including hiking)

Exclusion criteria:

Suffering from any chronic disease History of cognitive disorders or neurological diseases History of allergies and sensitivities Use of any sports supplements in the two months before the start of the study Smoking and alcohol consumption Donating blood in the 2 months before the start of the study History of staying at higher altitudes From 2000 meters in two months before the beginning of the research, sleeping at an altitude above 2700 meters in two weeks before the beginning of the research Taking acetazolamide drug in two weeks before the beginning of the research Allergy to acetazolamide and sulfonamides Suffering from color blindness.

Age

From **18 years** old to **44 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **12**

Actual sample size reached: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

Someone other than researcher 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 (ginkgo biloba 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 (ginkgo biloba 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 study subjects and researchers did not know who would take ginkgo biloba 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

2023-03-01, 1401/12/10

Ethics committee reference number

IR.RAZI.REC.1402.014

Health conditions studied

1

Description of health condition studied

The participants are healthy and trained male mountaineer.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Change in the time to reach exhaustion in a submaximal endurance exercise under hypoxic conditions
Timepoint
After administration of ginkgo biloba or placebo under hypoxic conditions
Method of measurement
Record time using a stopwatch

2

Description
Selective visual reaction time
Timepoint
At the beginning of the study to evaluate the level of cognitive function, after taking ginkgo biloba 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
Cognitive function
Timepoint
At the beginning of the study to evaluate the level of cognitive function, after taking ginkgo biloba or placebo and before and after applying hypoxia
Method of measurement
Using the color-word Stroop test

4

Description
sense of pleasure
Timepoint
Before and after reaching exhaustion in a submaximal endurance exercise under normobaric hypoxia conditions
Method of measurement
Using an 11-item emotion scale

5

Description
Arousal level
Timepoint
Before and after reaching exhaustion in a submaximal endurance exercise under normobaric hypoxia conditions
Method of measurement
Using a 6-item scale of perceived arousal

6

Description
The degree of perception of pressure
Timepoint
Before and after reaching exhaustion in a submaximal endurance exercise under normobaric hypoxia conditions
Method of measurement
Using a pressure perception scale of 6 to 20 borg

Secondary outcomes

empty

Intervention groups

1

Description
Ginkgo biloba group: Apart from the familiarization sessions and initial measurements, the subjects attend the laboratory twice and perform the Stroop test and reaction time in normal conditions and simulated altitude conditions and the submaximal aerobic test in simulated altitude conditions. . Subjects take ginkgo biloba for five days and take acetazolamide on the last day (the day before the test) and take the last dose of ginkgo biloba and acetazolamide on the day of the test. In other words, they consume ginkgo biloba for a period of five days. A one-week grace period will be considered.
Category
Treatment - Drugs

2

Description
placebo group: Apart from the familiarization sessions and initial measurements, the subjects attend the laboratory twice and perform the Stroop test and reaction time in normal conditions and simulated altitude conditions and the submaximal aerobic test in simulated altitude conditions. Subjects take for five days and take acetazolamide on the last day (the day before the test) and take the last dose of placebo and acetazolamide on the day of the test. In other words, they consume placebo for a period of five days. A one-week grace period will be considered.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi University
Full name of responsible person
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Sponsors / Funding sources

1

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Full name of responsible person
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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
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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