Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effects of Acute L-Theanine Supplementation on Muscle Damage, Physical Performance, and Cognitive Function Following a Session of Exhaustive Aerobic Activity in Female Athletes

Protocol summary

Study aim

The Effects of Acute L-Theanine Supplementation on Muscle Damage, Physical Performance, and Cognitive Function Following a Session of Exhaustive Aerobic Activity in Female Athletes

Design

A controlled clinical trial with parallel groups, double-blind, and randomized in a block design on 20 female athletes. The website www.randomization.com will be used for randomization.

Settings and conduct

This study will be conducted at Razi University. First, the research variables will be measured. Then, two groups of participants in the study will receive the desired interventions. After the interventions are completed, the research variables will be measured again. In this study, the participants and the main research team will be blinded. Capsules similar to L-theanine capsules will be used as placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Regularly engaged in aerobic exercise (≥4 sessions per week). No history of chronic disease or musculoskeletal injuries in the past 6 months. No supplement or medication use that may interfere with the study. Normal BMI (18.5-24.9 kg/m2). Exclusion criteria: Pregnant or lactating. Sensitivity to L-theanine History of neurological or cognitive disorders.

Intervention groups

1) Supplement = Participants are assessed before and after consuming one L-theanine capsule 2) Placebo (Control) = Participants are assessed before and after consuming one placebo capsule

Main outcome variables

Changes in muscle damage, physical and cognitive function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250403065192N1**
Registration date: **2025-05-09, 1404/02/19**
Registration timing: **prospective**

Last update: **2025-05-09, 1404/02/19**
Update count: **0**

Registration date

2025-05-09, 1404/02/19

Registrant information

Name
Simin Hadadi
Name of organization / entity
The University of Razi
Country
Iran (Islamic Republic of)
Phone
+98 83 4372 3734
Email address
siminhadadi91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-31, 1404/03/10

Expected recruitment end date

2025-06-10, 1404/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effects of Acute L-Theanine Supplementation on Muscle Damage, Physical Performance, and Cognitive Function Following a Session of Exhaustive Aerobic Activity in Female Athletes

Public title
Effects of acute L-theanine administration on muscle damage, physical and cognitive performance among female athletes.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Regularly engaged in aerobic exercise (≥4 sessions per week). No history of chronic disease or musculoskeletal injuries in the past 6 months. No supplement or medication use that may interfere with the study. Normal BMI (18.5-24.9 kg/m2). Age range 18 to 30 years

Exclusion criteria:
Pregnant or breastfeeding. Allergy to L-theanine History of neurological or cognitive disorders.

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the block randomization method will be used through the website www.randomization.com. For this purpose, first, each subject is assigned a number as a unique identification code and a 20-digit sequence (equal to the sample size) is created. Then, the names of the intervention groups including 1) exercise + supplement group; 2) exercise + placebo group; 3) supplement group; 4) control group will be defined in the relevant section of the website. After defining the groups and in order to prevent potential problems caused by blocking with fixed-size blocks, the method of randomly selecting blocks with different sizes will be used for blocking. In this case, with the sample size being known, the block sizes will be unequal and a multiple of the number of intervention groups (for example, blocks with sizes of 2, 4, 6 or 8). The website has the ability to randomly create sequences of blocks with different sizes. In the final step, by executing the Generate Plan command on the website, all subjects are randomly assigned to blocks of different sizes that themselves have a random sequence. Finally, by using the number (code) assigned to each subject and examining the blocks, the group of each subject will be determined.

Blinding (investigator's opinion)
Single blinded

Blinding description
The present study will be conducted in a single-blinded manner and participants will be kept blind to the supplement or placebo, while due to the nature of exercise training, blinding will not be done in this case (exercise intervention). In order to blind the two groups that do not receive L-theanine capsules, capsules similar to L-theanine capsules in terms of appearance, smell, taste and color will be used as placebos, and information about supplement and placebo intake will be kept secret from the subjects.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Razi University Ethics Committee

Street address
Room 49, Faculty of Sport Sciences, Razi University, Daneshgah St., Taq Bostan

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Approval date
2025-04-22, 1404/02/02

Ethics committee reference number
IR.RAZI.REC.1404.004

Health conditions studied

1

Description of health condition studied
Muscle injury

ICD-10 code
T06.4

ICD-10 code description
Injuries of muscles and tendons involving multiple body regions

Primary outcomes

1

Description
Muscle injury assessment

Timepoint
In two stages: before taking the supplement and immediately after completing the Bruce test.
Method of measurement
Through blood sampling

2

Description
Balance state
Timepoint
Before and after taking the supplement or placebo
Method of measurement
Using the Tecnobody device in two static and dynamic modes

3

Description
ارزیابی عملکرد شناختی
Timepoint
Before and after taking the supplement or placebo
Method of measurement
Using standard cognitive tests (Stroop test or working memory test), visual analog scale (VAS) for fatigue and muscle pain. Profile of Mood States Questionnaire (POMS)

4

Description
Physical performance assessment
Timepoint
Before and after taking the supplement or placebo
Method of measurement
vertical jump test to assess lower body strength, 20-meter sprint test to assess speed and anaerobic capacity, handgrip isometric strength test to assess upper body strength

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group of participants will receive L-theanine supplementation. Then, the Bruce Exhaustive Aerobic Test, Balance Test, Vertical Jump Test, 20-meter Speed Test, Isometric Hand Strength Test, Cognitive Function Test, Visual Analogue Scale (VAS) for Muscle Fatigue and Soreness, and the Profile of Mood States (POMS) Questionnaire will be used to evaluate the subjects. Blood sampling will also be performed in two stages, pre-test and post-test, to assess the extent of muscle damage.
Category
Other

2

Description
Control group: This group of participants will receive a placebo. Then, in order to evaluate the subjects, the Bruce Exhaustive Aerobic Test, Balance Test, Vertical Jump Test, 20-meter Speed Test, Isometric Hand Strength Test, Cognitive Function Test, Visual Analog Scale (VAS) for Muscle Fatigue and Soreness, and the Profile of Mood States (POMS) Questionnaire will be used. Also, in order to assess the extent of muscle damage, blood sampling will be performed in two stages, pre-test and post-test.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi University
Full name of responsible person
Rastegar Hoseini
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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
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
Rastegar Hoseini
Position
Assistant Professor
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Some data can be shared after de-identifying the subjects.
When the data will become available and for how

long

3 months after results are published

To whom data/document is available

All persons upon formal request

Under which criteria data/document could be used

Requests for access to data are permitted for any purpose.

From where data/document is obtainable

If you need to receive documents, please send an email to Rastegar Hoseini, a member of the Razi University faculty, at the email address: rastegar.hoseini@gmail.com.

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

In case of formal request, stating the relevant reasons and providing full details, the data will be sent via email after 72 hours.

Comments