

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effectiveness of capsules containing the combination of caffeine, L-theanine and piperin compared to pure caffeine and placebo in improving attention in healthy people

Protocol summary

Study aim

Investigating the effect of caffeine consumption alone versus caffeine plus theanine and piperine versus placebo in improving the concentration of healthy people

Design

Cross-over, double-blind, randomized, phase 2 clinical trial on 31 healthy subjects. The rand function of Excel software is used for randomization.

Settings and conduct

This study was conducted in the neurological laboratory of Rouzbeh State Hospital in Tehran, and blinding of the sample is done by the clinical expert supervising the project, and the researcher and the participants, by coding the drug or placebo envelope and receiving the capsule from the second researcher, have no information about They did not have the order of received interventions.

Participants/Inclusion and exclusion criteria

To enter the study, the participants must be at least 19 and at most 45 years old and consume at least 5 cups of tea or coffee during the week. Conditions of non-entry include pregnancy, breastfeeding, suffering from an acute illness.

Intervention groups

The first intervention group receives one capsule of three types of coded capsules containing 200 mg, the capsule containing 200 mg theanine, 150 mg caffeine and 20 mg piperine or a placebo capsule orally, and two days later, the second capsule and Three days later, he receives the third capsule orally. The second and third groups will also receive the same drugs randomly in three times.

Main outcome variables

Checking the total attention index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160306026938N19**

Registration date: **2024-02-19, 1402/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-19, 1402/11/30**

Update count: **0**

Registration date

2024-02-19, 1402/11/30

Registrant information

Name

Mahdi Vazirian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6412 1223

Email address

vazirian_m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-14, 1402/11/25

Expected recruitment end date

2024-03-15, 1402/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of capsules containing the combination of caffeine, L-theanine and piperin compared to pure caffeine and placebo in improving attention in healthy people	
Public title	Comparing the effectiveness of the combination of caffeine, L-theanine and piperin compared to placebo and pure caffeine in increasing attention
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Regular consumption of tea or coffee (at least five cups per week) Regular consumption of breakfast Normal or corrected-to-normal vision Body mass index between 20 and 30
Exclusion criteria:	Pregnancy or breastfeeding Having acute diseases (infectious or non-infectious) Suffering from incurable chronic diseases such as cancer or types of epilepsy Deficiency of immune system Smoking
Age	From 19 years old to 45 years old
Gender	Both
Phase	2-3
Groups that have been masked	- Participant - Investigator
Sample size	Target sample size: 31
Randomization (investigator's opinion)	N/A
Randomization description	
Blinding (investigator's opinion)	Double blinded
Blinding description	Participants: They all receive capsules of the same shape, same color, and same smell in all three experiments, and they cannot identify the difference in any way. Researcher: All the capsules are coded (in the envelope) and the researcher will not know about the nature of the codes of the medicine delivered to the subject and will only hand over the codes to subject to receive the medicine based on thje code from the second researcher.
Placebo	Used
Assignment	Crossover
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Tehran University of Medical Siences
Street address	Tehran University of Medical Sciences, Qods street corner, Keshavarz Blvd, Tehran, Iran.
City	Tehran
Province	Tehran
Postal code	1417653761
Approval date	2023-12-19, 1402/09/28
Ethics committee reference number	IR.TUMS.TIPS.REC.1402.131
Health conditions studied	
<u>1</u>	
Description of health condition studied	Attention and concentration deficit
ICD-10 code	R41.840
ICD-10 code description	Attention and concentration deficit
Primary outcomes	
<u>1</u>	
Description	Total attention score
Timepoint	Measuring attention at the beginning of the study (before the start of the intervention) and half an hour after taking the drug or placebo
Method of measurement	Integrated Visual and Auditory Continuous Performance Test
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: will receive 1- Caffeine capsule containing 200 milligrams of pure caffeine, 2- placebo (containing 300 mg starch) and 3- Caffeine + theanine + piperine capsule, containing 150 ml of caffeine, 200 mg of theanine and 10 mg of piperine, respectively, without knowing the nature of medicine or placebo, orally with an interval of one week for each capsule.
Category	Behavior

2

Description

Intervention group: will receive 1- placebo (containing 300 mg starch), 2- Caffeine capsule containing 200 milligrams of pure caffeine, and 3- Caffeine + theanine + piperine capsule, containing 150 ml of caffeine, 200 mg of theanine and 10 mg of piperine, respectively, without knowing the nature of medicine or placebo, orally with an interval of one week for each capsule.

Category

Behavior

3

Description

Intervention group: will receive 1- Caffeine + theanine + piperine capsule, containing 150 ml of caffeine, 200 mg of theanine and 10 mg of piperine 2- Caffeine capsule containing 200 milligrams of pure caffeine, and 3- placebo (containing 300 mg starch), respectively, without knowing the nature of medicine or placebo, orally with an interval of one week for each capsule.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Dr. Mahtab Motamed

Street address

Below Lashkar intersection, South Kargar Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 9151

Email

hosp_roozbeh@tums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Akbari Sari

Street address

Corner of Qods Street, Keshavarz Boulevard, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email

mehdivazirian@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

Position

PhD of Pharmacognosy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacognosy Lab., Second Floor, New building, Faculty of Pharmacy, In front of Oruji Alley, 16th Azar Ave., Enqelab Ave.

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6412 1223

Fax

Email

Vazirian_m@tums.ac.ir

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

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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

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

All data can be shared after de-identification.

When the data will become available and for how long

Access starts from 2026

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

Any type of analysis on the data is allowed, but they
cannot use it as a document for making a supplement or
medicine, or to prepare an article, solely based on the
results of this study.

From where data/document is obtainable

Dr. Mehdi Vazirian. Address: Advanced Research
Laboratory of Pharmacognosy, Second Floor, New
Building, Faculty of Pharmacy, Tehran University,
Enqelab St., Tehran, Iran. Contact number:
02166959101, E. mail: mehdivazirian@gmail.com.

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

Sending the official university application to Dr. Mehdi
Vazirian's email, checking the authenticity and
authenticity of the submitted application and sending the
documents to the applicant's email.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

Position

PhD of Pharmacognosy

Latest degree

Ph.D.

Other areas of specialty/work

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