Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

1

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

1

Description of health condition studied
Attention and concentration deficit
ICD-10 code
R41.840
ICD-10 code description
Attention and concentration deficit

Primary outcomes

1

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

1

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 buliding, 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

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Person responsible for updating data

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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, Enqebal 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