Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of brushing with caffeinated toothpaste on cognitive and motor responses of the central nervous system: A pilot study

Protocol summary

Study aim
Investigating the effect of brushing with caffeinated toothpaste on cognitive and motor responses of the central nervous system

Design
A clinical trial with a control group, with a placebo, a sample size of 75, double-blind, phase 3, randomized, RAND function in Excel is used for randomization.

Settings and conduct
During a public call, volunteers are invited to Fasa University of Medical Sciences. After explaining the study and receiving the informed consent, each person will be given a package containing a toothbrush, capsule and toothpaste. In the first phase, 50 people, including 5 groups of 10 people, will only take neuro-cognitive computer tests. In the second phase, 25 people, including 5 groups of 5 people, will measure the serum caffeine level.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: 1) Healthy subjects with informed consent to participate in the study 2) Absence of addiction to drugs, alcohol and tobacco 3) Not consuming coffee and painkillers containing caffeine, nerve agents, tea and drinks that can affect the tests, from 48 hours before. People who do not have: 4) cognitive impairment. 5) mental disorder. 6) cardiovascular diseases. 7) neurological disorders. 8) thyroid disorders. 9) mouth and mucous diseases. Exclusion criteria: 1) Any reaction or sensitivity to caffeine

Intervention groups
1. Receiving placebo capsule and toothbrush with control toothpaste 2. Receiving 100 mg caffeine capsule and toothbrush with control toothpaste 3. Receiving placebo capsule and toothbrush with caffeinated toothpaste 100 mg in 2 minutes 4. Receiving placebo capsule and toothbrush with caffeinated toothpaste 100 mg in 3 minutes 5.Receiving placebo capsule and toothbrush with 100 mg caffeinated toothpaste in 4 minutes

Main outcome variables
Selective attention capacity, Selective processing speed, Short-Term Memory and Hand Eye Coordination, serum caffeine

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230318057752N2**
Registration date: **2023-07-31, 1402/05/09**
Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**
Update count: **0**

Registration date
2023-07-31, 1402/05/09

Registrant information
Name
Kiarash Zare
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-23, 1402/06/01
Expected recruitment end date
2023-11-22, 1402/09/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of brushing with caffeinated toothpaste on cognitive and motor responses of the central nervous system: A pilot study

Public title
Investigating the effect of caffeine on cognitive and motor responses
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy people with informed consent to participate in the study
Exclusion criteria:
Any reaction or sensitivity to caffeine Addicted to drugs, alcohol and tobacco Consuming coffee and painkillers containing caffeine, nerve agents, tea and drinks that can affect the tests, from 48 hours before Cognitive disorders Mental disorders Cardiovascular diseases Neurological disorders Thyroid disorders Mouth or mucous membrane diseases
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization of people is done based on the permutation of five random blocks, and the random sequence based on this method will be done by lottery using a table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blocking and allocation sequence for concealment will be done by a person not involved in the research. The shape and packaging of the capsules and toothpaste will be the same so that the researchers and participants will not be aware of the package (one capsule and one toothpaste) of each person. Only the person responsible for packaging the drugs will know the numbers of the respective envelopes, and none of the researchers or participants will know the contents of the package that each person receives. Packages will be placed in A, B, C, D and E envelopes by a person as a coder. Patients will not be aware of the assignment of codes to package envelopes, and the researchers who will provide the packages to the people at the place of implementation of the plan will not be aware of the contents of the packages and the allocation of people to five groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Fasa University of Medical Sciences
Street address
Ibn Sina square, Fasa
City
Fasa
Province
Fars
Postal code
7461686688
Approval date
2023-06-25, 1402/04/04
Ethics committee reference number
IR.FUMS.REC.1402.042

Health conditions studied

1

Description of health condition studied
Cognitive and motor responses of the central nervous system
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Selective attention capacity
Timepoint
Before receiving caffeine, 10, 30 and 60 minutes after receiving caffeine
Method of measurement
Using computer tests

2

Description
Selective processing speed
Timepoint
Before receiving caffeine, 10, 30 and 60 minutes after

receiving caffeine

Method of measurement

Using computer tests

3

Description

Short-Term Memory

Timepoint

Before receiving caffeine, 10, 30 and 60 minutes after receiving caffeine

Method of measurement

Using computer tests

4

Description

Hand Eye Coordination

Timepoint

Before receiving caffeine, 10, 30 and 60 minutes after receiving caffeine

Method of measurement

Using computer tests

5

Description

Serum caffeine level

Timepoint

10, 30 and 60 minutes after receiving caffeine

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group receiving placebo capsule and toothbrush with 100mg caffeinated toothpaste for 2 minutes

Category

Other

2

Description

Intervention group: The group receiving placebo capsule and toothbrush with 100mg caffeinated toothpaste for 3 minutes

Category

Other

3

Description

Intervention group: The group receiving placebo capsule and toothbrush with 100mg caffeinated toothpaste for 4 minutes

Category

Other

4

Description

Control group: The group receiving 100mg caffeine capsule and toothbrush with regular toothpaste for 2 minutes

Category

Other

5

Description

Control group: The group receiving placebo capsule and toothbrush with normal toothpaste for 2 minutes

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fasa University of Medical Sciences

Full name of responsible person

Kiarash Zare

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

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

Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Kiarash Zare

Position

Expert

Latest degree

Bachelor

Other areas of specialty/work

Laboratory Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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

Demographic information and clinical trial results

When the data will become available and for how long

3 months after the publication of the article, it will be possible to access the data.

To whom data/document is available

Researchers in all universities of medical sciences

Under which criteria data/document could be used

Researchers can submit their request to the Vice-Chancellor of Research and Technology and the Ethics Committee of Fasa University of Medical Sciences, and if they agree, the data will be provided to them.

From where data/document is obtainable

Fasa University of Medical Sciences, Vice President of Research and Technology

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

Approval of the Research and Technology Vice-Chancellor and Ethics Committee of Fasa University of Medical Sciences

Comments