Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Caffeine on Choroidal Thickness, Vascularization index, and Anterior Segment Parameters of the Eye in healthy population

Protocol summary

Study aim

Investigating changes in choroidal thickness and choroidal angiogenesis and investigating changes in anterior segment factors before and after consuming caffeinated and non-caffeinated beverages

Design

A clinical trial using people from the intervention group before the intervention as a control group, one-way blinding, phase 1, on 50 patients.

Settings and conduct

In this study, the selected people will drink coffee without caffeine one day and drink coffee with caffeine on another day. Imaging will also be done once before drinking coffee and then one hour, two, three and four hours after drinking coffee. Also, one-way blinding will be done and the people present in the study will not know the type of coffee used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Eye health in routine examinations Not using hard contact lenses in the last month Not using soft contact lenses in the last two weeks Personal consent to participate in the research project Not consuming coffee at least 4 hours before attending the program No smoking Do not drink coffee or any caffeinated drinks while studying Exclusion criteria: History of systemic and ophthalmic disease People with cardiac arrhythmia History of hypertension, diabetes, glaucoma, uveitis Pregnancy and breastfeeding Taking drugs that affect the posterior and anterior segment History of eye surgery

Intervention groups

All participants will be subjected to the intervention by drinking caffeinated and decaffeinated coffee on two days. The control group is also the people of the intervention group, which will be completely compared the day before the intervention.

Main outcome variables

Choroidal vascularity index؛ Angle-opening distance؛ Trabecular iris angle؛ Trabecular iris space area؛ Anterior chamber depth؛ Choroidal and Corneal thickness؛ Choroidal luminal and stromal thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231031059914N1**
Registration date: **2023-11-13, 1402/08/22**
Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**
Update count: **0**

Registration date

2023-11-13, 1402/08/22

Registrant information

Name
Niloofar Irandoost

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3322 5633

Email address
irandoustn4012@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Caffeine on Choroidal Thickness, Vascularization index, and Anterior Segment Parameters of the Eye in healthy population

Public title
Effect of Coffee on Eye
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ocular health in normal examination Not using hard contact lenses in the last month Not using soft contact lenses in the last two weeks Personal consent to participate in the research project Not consuming coffee at least 4 hours before attending the program No smoking Not drinking coffee or any caffeinated drinks during the test
Exclusion criteria:
History of systemic and ophthalmic disease People with cardiac arrhythmia History of hypertension, diabetes, glaucoma, uveitis Pregnancy and breastfeeding Taking medications that affect posterior and anterior segment of the eye History of eye surgery
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the participants will be unaware of the presence or absence of caffeine in each phase of the study.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Mashhad University of Medical Sciences
Street address
Qureishi Building, Daneshgah Street, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
۱۳۹۴۴ ۹۱۳۸۸
Approval date
2023-10-07, 1402/07/15
Ethics committee reference number
IR.MUMS.REC.1402.197

Health conditions studied

1

Description of health condition studied
Choroidal thickness changes
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Changes in anterior segment factors
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Changes in choroidal vascular index
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Choroidal vascularity index
Timepoint
Before intervention and 1, 2, 3, and 4 hours after intervention
Method of measurement
Posterior and anterior optical coherence tomography

2

Description
Angle-opening distance
Timepoint
Before intervention and 1, 2, 3, and 4 hours after intervention
Method of measurement
Posterior and anterior optical coherence tomography

3

Description
Trabecular iris angle
Timepoint
Before intervention and 1, 2, 3, and 4 hours after intervention
Method of measurement
Posterior and anterior optical coherence tomography

4

Description
Trabecular iris space area
Timepoint
Before intervention and 1, 2, 3, and 4 hours after intervention
Method of measurement
Posterior and anterior optical coherence tomography

5

Description
Anterior chamber depth
Timepoint
Before intervention and 1, 2, 3, and 4 hours after intervention
Method of measurement
Posterior and anterior optical coherence tomography

6

Description
Choroidal thickness
Timepoint
Before intervention and 1, 2, 3, and 4 hours after intervention
Method of measurement
Posterior and anterior optical coherence tomography

7

Description
Corneal thickness
Timepoint
Before intervention and 1, 2, 3, and 4 hours after intervention
Method of measurement
Posterior and anterior optical coherence tomography

8

Description
Choroidal luminal thickness
Timepoint
Before intervention and 1, 2, 3, and 4 hours after intervention
Method of measurement
Posterior and anterior optical coherence tomography

9

Description
Choroidal stromal thickness
Timepoint
Before intervention and 1, 2, 3, and 4 hours after intervention
Method of measurement
Posterior and anterior optical coherence tomography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: These people are given caffeinated coffee.
Category
N/A

2

Description
Control group: These people are given decaffeinated coffee.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam-Al-Anbia eye hospital
Full name of responsible person
Asieh Ehsaei
Street address
Abutaleb junction, Gharani Blvd, Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour-Mobarhan
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Qureshi Building, Daneshgah Street, Mashhad
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Iman Varshovi-Jaghargh
Position
Master of Science
Latest degree
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The non-identified information of people will be accessible to people after the publication of the article.

When the data will become available and for how long

The access period starts 3 months after the publication of the article

To whom data/document is available

The public will be allowed to access the information.

Under which criteria data/document could be used

For all scientific requests, documents can be used.

From where data/document is obtainable

Contact the following Email: I.Varshovi@Gmail.com

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

The request will be sent to the individual within one month after being raised in the clinical trial scientific group.

Comments