

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

Nilloofar 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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ramresearch@mums.ac.ir

**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**

Master

**Other areas of specialty/work**

Optometry

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**Latest degree**

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**Other areas of specialty/work**

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niloofar.irandoosr@gmail.com

**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**