

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Investigating the effect of Fampiridine on visual parameters and optic nerve imaging in patients with Anterior Ischemic Optic neuropathy

#### Protocol summary

##### Study aim

Determining the effect of fampiridine on visual parameters and optic nerve imaging in patients with anterior ischemic optic neuropathy.

##### Design

A controlled, parallel-group, no blinded, randomized phase 3 clinical trial on 40 patients. The envelope method will be used for randomization.

##### Settings and conduct

This study will be conducted at Shahid Beheshti University of Medical Sciences Institute of Eye and Vision Sciences on patients with anterior ischemic optic neuropathy. A group of patients receive only routine care. In addition to routine care, the second group will receive 10 mg fampiridine tablets for 12 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with anterior ischemic optic neuropathy; Consent to participate in the study; At least 3 months have passed since the onset of symptoms No inclusion criteria: Pregnancy; History of seizures; Renal failure

##### Intervention groups

Intervention group: In addition to standard treatment and control of underlying risk factors such as diabetes and blood pressure, they will be treated with 10 mg fampiridine tablets for 12 weeks (one tablet every 12 hours, the first week and 2 tablets from the second week onwards). Control group: They will receive only standard treatment and control of underlying risk factors such as diabetes and blood pressure

##### Main outcome variables

Changes in optic nerve cell thickness, visual parameters and optic nerve imaging

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151123025202N35**

Registration date: **2024-02-07, 1402/11/18**

Registration timing: **prospective**

Last update: **2024-02-07, 1402/11/18**

Update count: **0**

##### Registration date

2024-02-07, 1402/11/18

##### Registrant information

###### Name

Abbas Moradi

###### Name of organization / entity

Hamedan University of Medical Of Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 0097

###### Email address

a.moradi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-20, 1403/01/01

##### Expected recruitment end date

2024-09-21, 1403/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of Fampiridine on visual parameters and optic nerve imaging in patients with Anterior Ischemic Optic neuropathy

**Public title**

The effect of fampiridine on optic nerve imaging in patients with Anterior Ischemic Optic neuropathy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with anterior ischemic optic neuropathy Consent to participate in the study At least 3 months have passed since the onset of symptoms

**Exclusion criteria:**

Pregnancy History of seizures Renal failure

**Age**

No age limit

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

40 cards will be prepared, 20 cards with letter I (meaning intervention) and 20 cards with letter C (meaning control) and each one is placed in an envelope with aluminum foil and the lid is glued and placed inside a box. to give At the time of patients' arrival, one of the letter envelopes will be randomly selected and opened. According to the selected letter, the patient will be assigned to the intervention or non-intervention group

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

Next to Taleghani Hospital, Shahid Abbas Arabi Street (Parvaneh), Yemen Street, Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2023-07-17, 1402/04/26

**Ethics committee reference number**

IR.SBMU.ORG.1402.006

**Health conditions studied****1****Description of health condition studied**

Anterior Ischemic Optic neuropathy

**ICD-10 code**

H47.01

**ICD-10 code description**

Ischemic optic neuropathy

**Primary outcomes****1****Description**

Acuity Visual

**Timepoint**

Pre treatment and 12 weeks post treatment

**Method of measurement**

Using ETDRS chart

**2****Description**

Field of vision

**Timepoint**

Pre treatment and 12 weeks post treatment

**Method of measurement**

Using automatic perimetry device

**Secondary outcomes****1****Description**

Change in thickness of nerve cells

**Timepoint**

Pre treatment and 12 weeks post treatment.

**Method of measurement**

Using Peripapillary-OCT

**Intervention groups****1****Description**

Intervention group: In addition to standard treatment and control of underlying risk factors such as diabetes and blood pressure, they will be treated with 10 mg fampiridine tablets for 12 weeks (one tablet every 12 hours, the first week and 2 tablets from the second week onwards).

**Category**

Treatment - Drugs

## 2

### Description

Control group: They will receive only standard treatment and control of underlying risk factors such as diabetes and blood pressure

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Labafinejad Hospital

##### Full name of responsible person

dr Bita Shalbafian

##### Street address

Alongside Ayatollah Taleghani Hospital, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۶۶۶۶۳۱۱۱

##### Phone

+98 21 23871

##### Email

info@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr. Seyedeh Mehri Hamidi Sangdehi

##### Street address

Daneshjoo Blvd, Shahid Shahriari Square, Yemen St, Shahid Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

##### Phone

+98 21 2990 2067

##### Email

resvp@sbu.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Shahid Beheshti 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Abbas Moradi

##### Position

Coach

##### Latest degree

Master

##### Other areas of specialty/work

Epidemiology

##### Street address

Shahid fahmideh

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6517838736

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a.moradi@umsha.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Mohadese Feizi

##### Position

Ophthalmologist

##### Latest degree

Specialist

##### Other areas of specialty/work

Ophthalmology

##### Street address

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Abbas Moradi

**Position**

Coach

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Shahid fahmideh

**City**

Hamadan

**Province**

Hamadan

**Postal code**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more Information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available