

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)

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+98 81 3838 0097

Email address

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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

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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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Ophthalmologist

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Latest degree

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Other areas of specialty/work

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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