

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparing the neuroprotective effect of Brimonidine and placebo on visual indices in optic neuritis patients

Protocol summary

Study aim

Determining the neuroprotective effect of Brimonidine and placebo on visual indicators in optic neuritis patients

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, phase 3 on 60 patients, R statistical software was used for randomization.

Settings and conduct

After understanding the patients and obtaining a written consent, the patients are voluntarily directed to the Optometry Department of Zahra Zahedan Ophthalmology Hospital, where the best corrected visual acuity of both eyes, contrast sensitivity, and color vision are taken. Also, in order to conduct the study in a blinded manner and to prevent bias from the patients, brimonidine drops and placebo will be used in the patients in the same and similar appearance and with certain coding. The studied patients were divided into two groups receiving brimonidine and not receiving brimonidine, in the group of patients they will receive 0.2% brimonidine eye drops for 3 months. All patients in both groups, one month and 3 months later, will perform all visual indicators again in the described way.

Participants/Inclusion and exclusion criteria

All patients with acute optic neuritis referred to Zahedan alzahra Ophthalmology Hospital from the age of 18 to 45 years who do not have a previous neurological history and drugs that weaken the immune system.

Intervention groups

Intervention group for whom brimonidine drops and routine measures are prescribed. control group for whom routine measures are prescribed.

Main outcome variables

Visual acuity; Visual contrast; Color vision

General information

Reason for update

Acronym

ENEB

IRCT registration information

IRCT registration number: **IRCT20221127056631N1**

Registration date: **2022-12-03, 1401/09/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-03, 1401/09/12**

Update count: **0**

Registration date

2022-12-03, 1401/09/12

Registrant information

Name

mahdi asani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3230 3035

Email address

dr.mahdiasani@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-03-01, 1401/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the neuroprotective effect of Brimonidine and placebo on visual indices in optic neuritis patients

Public title

Evaluation of neuroprotective effect of Brimonidine on visual indices in optic neuritis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed and free consent to participate in the study
Acute optic neuritis The age range of patients is 18 to 45 years Spherical equivalent refractive error of three diopters of myopia to one and a half diopters of hyperopia

Exclusion criteria:

History of optic neuritis in another normal eye Use or history of using drugs affecting the immune system
History of any type of retinal surgery History of optic disc swelling in each eye Having amblyopia in one or both eyes Glaucoma Diabetic retinopathy or any type of maculopathy Color blindness

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation of patients to two groups is done by the permutation block stratified randomization method. First, eligible referring patients are classified according to age and gender in the order of arrival. Then they are assigned to the desired group based on blocks of 4 (consisting of two groups A and B and two repetitions for each) randomly selected from among all the possible states of permutations.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blinding method is used in this research. So that the patient will not be aware of the intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of zahedan University of Medical Sciences

Street address

Medical Sciences Campus., Dr. Hasabi Square., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9813637461

Approval date

2022-04-10, 1401/01/21

Ethics committee reference number

IR.ZAUMS.REC.1401.099

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

Optic neuritis

ICD-10 code

H46

ICD-10 code description

Optic neuritis

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

Visual acuity

Timepoint

Measurement on the first day and one month later and three months later

Method of measurement

Visual acuity measured by Snellen's chart.

2**Description**

Contrast sensitivity

Timepoint

Measurement on the first day and one month later and three months later.

Method of measurement

Contrast sensitivity measured by Young's chart.

3**Description**

Color vision

Timepoint

Measurement on the first day and one month later and three months later

Method of measurement

Color vision as measured by the Ishihara chart.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine interventions and brimonidine drops 0.2%

Category

Treatment - Drugs

2

Description

Control group: Routine interventions and artificial tear placebo drops

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Alzahra Eye Hospital

Full name of responsible person

Mahdi Asani

Street address

Motahari Blvd., Zhedan

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alzahra.eye@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Zahedan University of Medical Scinsces

Street address

Campus of Zahedan University of Medical Sciences

City

zahedan

Province

Sistan-va-Balouchestan

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zaums@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

5

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

Zahedan University of Medical Sciences

Full name of responsible person

Mahdi Asani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

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Subspecialist

Other areas of specialty/work

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Email

Dr.mahdiasani@yahoo.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

All data

When the data will become available and for how long

All time

To whom data/document is available

All person

Under which criteria data/document could be used

To improve the treatment and research process

From where data/document is obtainable

Contact my personal email at Dr.mahdiasani@yahoo.com or phone number 00989117721785 in the name of Dr. Asani so that the information can be sent to them as a file.

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

Information will be sent about ten days after the email

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Mahdi Asani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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