Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

The study of Optical coherence tomography and Optical coherence tomography angiography of the patients with Non-Arteritic Anterior Ischemic Optic Neuropathy before and after receiving Citicoline

Protocol summary

Study aim
Determination of the effect of Citicoline on OCTA and OCT in patients with anterior non-arterial optic nerve neuropathy (NAION)

Design
Patients are selected as case series. Approximately 20 patients are selected and given medication.

Settings and conduct
The leading study will be a prospective study which will be conducted in 1402 at the ophthalmology clinic of Khalili Hospital in Shiraz. This is a pre- and post-clinical trial study. The study population are patients with anterior optic nerve neuropathy based on inclusion criteria. In this group, citicoline ampule with a dose of 500 mg is injected intramuscularly once a week for 3 weeks. Patients undergo paraclinical examinations in the first week of AION attack and one month after starting treatment.

Participants/Inclusion and exclusion criteria
The patient is in the first week of the attack. 2. Age: Older than 18 years 3. Not taking Citicoline drug in the past three months, as well as antioxidants and multivitamins and having a special diet 4. Failure to receive previous treatment 5. Absence of congenital and acquired retinal diseases 6. Absence of ocular pathology such as glaucoma, retinal disease and uveitis 7. No corticosteroid drugs 8. Lack of Levodopa

Intervention groups
For the experimental group, the drug is prescribed. In this group, citicoline ampule with a dose of 500 mg is injected intramuscularly once a week for 3 weeks. Patients will undergo paraclinical examinations during the first week of AION attack and one month after starting treatment.

Main outcome variables
the thickness of the ganglion cell layer; the thickness of the optic nerve fiber layer; SVC thickness in OCTA; SVC thickness in OCTA; retinal thickness in OCTA; Choroidal thickness in OCTA

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240107060637N1**
Registration date: **2024-01-28, 1402/11/08**
Registration timing: **retrospective**

Last update: **2024-01-28, 1402/11/08**
Update count: **0**

Registration date
2024-01-28, 1402/11/08

Registrant information

Name
Mohammad reza Khalili

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3230 2830

Email address
khalilimr57@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-10, 1402/10/20

Expected recruitment end date
2024-01-13, 1402/10/23

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of Optical coherence tomography and Optical coherence tomography angiography of the patients with Non-Arteritic Anterior Ischemic Optic Neuropathy before and after receiving Citicoline

Public title

the effect of Citicoline on the retina in Non-Arteritic Anterior Ischemic Optic Neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient is in the first week of the attack Age: Older than 18 years

Exclusion criteria:

Consumption of Citicoline in the last three months as well as antioxidants and multivitamins and having a special diet Receiving previous treatment Congenital and acquired retinal diseases Presence of ocular pathology such as glaucoma, retinal disease and uveitis Taking corticosteroid drugs Taking Levodopa

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2024-01-03, 1402/10/13

Ethics committee reference number

IR.SUMS.MED.REC.1402.468

Health conditions studied

1

Description of health condition studied

Non-Arteritic Anterior Ischemic Optic Neuropathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of damage in the thickness of the ganglion cell layer and optic nerve fiber layer is reduced in OCT images of the patient before and after receiving citicoline.2. Vascular density in OCTA should not be reduced.

Timepoint

Patients will undergo paraclinical examinations during the first week of AION attack and one month after the start of treatment

Method of measurement

Optical coherence tomography and Optical coherence tomography angiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, Citicoline ampule with a dose of 500 mg is injected intramuscularly once a week for 3 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Dr Mohammadreza Khalili
Street address
Khalilii St, Mollasadra St
City
Shiraz
Province
Fars
Postal code
7193616641
Phone
+98 71 3627 1382
Email
khalili@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mohammadhashem Hashempour
Street address
Shiraz University of Medical Sciences, Zand St
City
Shiraz
Province
Fars
Postal code
7134853185
Phone
+98 71 3230 5410
Email
info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad reza Khalili
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Zand St., Stad block, in front of the Medical School, Poostachi Ophthalmology Research Center
City
Shiraz
Province
Fars
Postal code
7134997446
Phone
+98 71 3230 2830
Fax
Email
khalilimr57@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad reza Khalili
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Zand St., Stad block, in front of the Medical School, Poostachi Ophthalmology Research Center
City
Shiraz
Province
Fars
Postal code
7134997446
Phone
+98 71 3230 2830
Fax
Email
khalilimr57@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad reza Khalili
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology

Street address
Zand St., Stad block, in front of the Medical School, Poostachi Ophthalmology Research Center
City
Shiraz
Province
Fars
Postal code
7134997446
Phone
+98 71 3230 2830
Fax
Email
khalilimr57@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
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information about the main outcome is shared after making people unidentifiable.
When the data will become available and for how long
Starting the access period from the date of publication of the results up to 5 years later
To whom data/document is available
Researchers and people working in the pharmaceutical industry
Under which criteria data/document could be used
Those who intend to produce, prescribe and research this drug
From where data/document is obtainable
khalilimr57@gmail.com Dr Mohammadreza Khalili
What processes are involved for a request to access data/document
Examination and receiving of medication by patients for one month Collecting OCTA and OCT photos for one month.
Comments