Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of effect of fluoxetine on the clinical prognosis in patients with anterior ischemic optic neuropathy (AION) according to evaluations of visual acuity and VEP tests as main outcomes, in comparison between drug and placebo groups.

Protocol summary

Study aim
1)Evaluation of effect of fluoxetine on the clinical prognosis in patients with AION 2) Evaluation of demographic parameters in those patients

Design
Randomized clinical trial containing placebo, a double blinded study

Settings and conduct
Patients with AION who sign the agreement papers, divide randomly in groups of 50 according to inclusion and exclusion criteria. Firstly, each patient completes the questionnaires for evaluate the demographic parameters. Then patients, besides receiving the main treatment for them disease according to guideline, randomly divide into two groups former the receivers of fluoxetine and later the receivers of placebo. Then according to evaluation protocol undergo: physical examination, fundoscopy, NLR, DSM-5 and HAM-D Questionnaires, VEP and OCT. Patient and interviewer are blinded but analyzer now which patient receive placebo and which patient receive the drug. This research will conduct in ophthalmology research center of Rasool Akram hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian Age over 18 Patients with non-arteritic AION Exclusion criteria: 1) Pregnancy 2) History of cataract, glaucoma, congenital eye disease, collagen vascular, immunologic disease, psychological disease 3) Fluoxetine or other psychological medications 4) GCA, CRP + or ESR >= 40 5) Trauma or surgery of eye 6) More than 3 weeks delay of visit from onset of disease 7) No positive improvement in the score of depression questionnaires in comparison between 1th and last visit. 8) Disagreement on using fluoxetine or continue study or death of patient

Intervention groups
Patients with AION in two groups: 1) Patients given fluoxetine 2) Patients given placebo

Main outcome variables
Visual acuity; VEP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181109041596N1**
Registration date: **2019-01-07, 1397/10/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-07, 1397/10/17**
Update count: **0**

Registration date
2019-01-07, 1397/10/17

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of fluoxetine on the clinical prognosis in patients with anterior ischemic optic neuropathy (AION) according to evaluations of visual acuity and VEP tests as main outcomes, in comparison between drug and placebo groups.

Public title

Evaluation of effect of fluoxetine on the clinical prognosis in patients with anterior ischemic optic neuropathy (AION)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian patients Age over 18 years old Patients with diagnosis of AION; non-arteritic type

Exclusion criteria:

Pregnancy before or during study Past medical history of cataract, glaucoma (open or close angle) congenital eye disease such as cloboma and involvement with disease effecting the central visual field of patient Patients with past medication history of using fluoxetine or other psychological medications including antidepressants Patients suffering from psychological disease Patients who use medications including :arthemeter، astemizol, cisapride, eliglustat, goserelin, isocarboxazide, artemether, leuprolide, linezolid, lumefantrine, methylene blue, phenelzine, pimozide, procarbazine, selegiline, thioridazine, tranylcypromine Patients diagnosed with immunologic and collagen vascular disease Patients with symptoms of or diagnosed with giant cell arteritis and positive CRP more than 3+ or ESR more than 40 Trauma or surgery history of eyes Duration between involvement and interview more than 3 weeks Patients without compliance of using fluoxetine or disagrement of patient to continue accompanying the study Involvement by glaucoma Involvement by cataract Change in depression questionnaire score lower than 1 score in comparison to first and forth visit (means the poor compliance of patient that has not used fluoxetine Death of patient

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize allocation of patients in each group of study, we'll use the permuted block randomization method by means of blocks with 4 in size. According to the number of patients in each group of study (100 patients in each group), 25 blocks of four by means of online website (www.sealedenvelope.com) will produce. For concealment, during randomization we'll use specific codes written on drug or placebo boxes which have been produced by computer. Each patient who enters the study will receive a box of drug or placebo according to the

Blinding (investigator's opinion)

Double blinded

Blinding description

During this study, participant will not be aware about if he receiving the drug or placebo because the shape and other features of boxes of both drugs and placebos are the same. The interviewer and investigator also will not be aware of which patients have received drug or placebo. But the analyzer knows the patients who received drug and the patients who received placebo.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of medicine faculty of Iran university of medical science

Street address

Faculty of medicine, Iran university of medical science, Hemmat highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-10-23, 1397/08/01

Ethics committee reference number

IR.IUMS.FMD.REC.1397.093

Health conditions studied

1

Description of health condition studied
AION; Anterior ischemic optic neuropathy: is a condition in which the optic nerve is affected by ischemia at its anterior section (intraocular), AION has two types: arteritic and non arteritic types. arteritic type dominantly results from giant cell arteritis. The etiologies suggested for non arteritic type contains: diabetes mellitus, hypertension and obstructive sleep apnea. This research spends to non arteritic type of disease.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
1)Visual acuity: visual acuity of each patient will measure by snelene chart. 2)Result of VEP test: both time(latency) and voltage parameters of VEP test will measure.
Timepoint
1)Visual acuity: in first visit and 6th month after initiation of treatment 2)VEP: in first visit and 6th month after initiation of treatment
Method of measurement
1)Visual acuity: snelene chart 2)VEP test by means of VEP device

Secondary outcomes

1

Description
1)NLR: neutrophil to lymphocyte ratio 2)OC: thickness of retina 3)Perimetry: percent of scotoma in visual field 4)Depression score 5)demographic informations (age, gender, profession & etc.)
Timepoint
1)NLR: In first visit and 6th month after initiation of treatment 2)OCT: In first visit and 6th month after initiation of treatment 3)Perimetry: In first visit and 6th month after initiation of treatment 4)Depression score: In first visit and 6th month after initiation of treatment 5)Demographic information (age, gender, profession & etc.): at first visit
Method of measurement
1)NLR: CBC diff 2)OCT: OCT device 3)Perimetry: digital perimetry device 4)Depression score: DSM 5 questionnaire 5)Demographic information (age, gender, profession & etc.): by means of personal information and epidemiology questionnaires.

Intervention groups

1

Description
Intervention group: receivers of fluoxetine antidepressant, 20 mg daily
Category
Treatment - Drugs

2

Description
Control group: Receivers of placebo of fluoxetine that are resemble exactly in appearance features to fluoxetine.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ophthalmology research center of Rasool Akram hospital
Full name of responsible person
Dr Mostafa Soltan Sanjari
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Ophthalmology research center of Rasool Akram hospital, Rasool Akram hospital, Nyayesh street, Sattarkhan, Tehran
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Eye research center of Rasool Akram hospital - Iran university of medical science
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
Iran University of Medical Sciences
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Position
Medical student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available