Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation of effect of treatment by fluoxetine on clinical prognosis in patients with Optic neuritis in comparison between drug and placebo groups.

Protocol summary

Study aim
Evaluation of effect of fluoxetine on the clinical prognosis of Optic neuritis

Design
Randomized clinical trial containing placebo, a double blinded study

Settings and conduct
A hundred patients with Optic neuritis referred to Rasool Akram hospital ophthalmology clinic will be randomly divided equally in drug and placebo study groups. Subjects will be evaluated at the first visit and on the end of the 6th month of the treatment course by physical examination, fundoscopic evaluation, VEP, OCT and perimetry batteries. Patient and interviewer are blinded from the treatment received by patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1)Iranian 2)Age over 18 3)Patients with Optic neuritis Exclusion criteria: 1) Pregnancy 2) History of cataract, glaucoma, congenital eye diseases 3) Fluoxetine or other psychotherapeutics medication history 4) More than 3 weeks delay from onset of the visual signs

Intervention groups
Patients with optic neuritis in two groups: 1)Patients given fluoxetine 20 mg daily 2)Patients given placebo

Main outcome variables
Visual acuity; VEP (Visual evoked potential)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200719048138N1**
Registration date: **2020-10-19, 1399/07/28**
Registration timing: **retrospective**
Last update: **2020-10-19, 1399/07/28**
Update count: **0**

Registration date
2020-10-19, 1399/07/28

Registrant information

Name
Mostafa Soltan Sanjari

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
2019-10-04, 1398/07/12

Expected recruitment end date
2020-09-02, 1399/06/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of effect of treatment by fluoxetine on clinical prognosis in patients with Optic neuritis in comparison between drug and placebo groups.

Public title
Evaluation of effect of fluoxetine on the clinical prognosis in patients with Optic neuritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian patients Age over 18 years old Patients diagnosed with Optic neuritis

Exclusion criteria:

History of multiple sclerosis cataract, glaucoma (open or close angle) congenital eye diseases such as coloboma and involvement with other disorders effecting the central visual field Patients with past medication history of using fluoxetine or other psychotherapeutics including antidepressants psychological disease medication history of arthemeter، astemizol, cisapride, eliglustat, goserelin, isocarboxazide, artemether, leuprolide, linezolid, lumefantrine, methylene blue, phenelzine, pimozide, procarbazine, selegiline, thioridazine, tranylcypromine Patients diagnosed with autoimmune and collagen vascular diseases Trauma or history of ophthalmologic surgeries Interval between involvement and interview more than 3 weeks Pregnancy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

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 (50 patients in each group and over all 100 cases in the study), 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 the Iran University of Medical Sciences

Street address

Iran University of Medical Sciences (IUMS), Hemmat highway, Tehran, iran

City

Tehran

Province

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1449614535

Approval date

2020-04-11, 1399/01/23

Ethics committee reference number

IR.IUMS.REC.1399.083

Health conditions studied

1

Description of health condition studied

The Optic neuritis

ICD-10 code

H46

ICD-10 code description

Optic neuritis

Primary outcomes

1

Description

1)Visual acuity: precision of vision assessed by snelene chart.

Timepoint

On first visit and 6th month after initiation of treatment

Method of measurement

Visual acuity: snelene chart

2

Description

VEP (Visual evoked potential) test: both time (latency) and amplitude parameters of VEP test will measure.

Timepoint

On first visit and 6th month after initiation of treatment

Method of measurement

VEP test by means of VEP device

Secondary outcomes

1

Description
OCT: thickness of retina
Timepoint
OCT: on first visit and 6th month after initiation of treatment
Method of measurement
OCT: OCT device

2

Description
Perimetry: percent of scotoma in visual field
Timepoint
Perimetry: On first visit and 6th month after initiation of treatment
Method of measurement
Perimetry: digital perimetry device

Intervention groups

1

Description
Intervention group: Intervention group: receivers of fluoxetine antidepressant, 20 mg daily for 6 month
Category
Treatment - Drugs

2

Description
Control group: Control group: Receivers of placebo of fluoxetine that are resemble exactly in appearance features to fluoxetine for 6 month
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Vice chancellor for research and technology of the Iran University Of Medical Sciences (IUMS)
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
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Latest degree
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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