Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of fluoxetine on visual acuity and VEP indices in amblyopia patients over 18 years of age

Protocol summary

Study aim

The effect of fluoxetine on improving indicators VEP visual acuity and amblyopia in patients over 18 years between 2016 to 2018 at Farabi Hospital in Tehran

Design

This study is a randomized clinical trial (RCT). Amblyopia patients over 18 years of age who come to the Farabi Hospital from 1993 to 2013 will be included in the study if they have entry criteria and no exclusion criteria. For all patients, BCVA and VEP are initially requested and registered. The patients are then randomly divided into two groups, the group receiving fluoxetine and the group that received the placebo. This study is done in Double-blind. Patients are treated for a period of 90 days and then the results of VEP and BCVA are reviewed and compared to the previous results. Intervention group: Fluoxetine 20 mg, Control group: Placebo

Settings and conduct

The study is double-blind study of patients in the study, the type of drug are blind and do not know that fluoxetine or placebo consumption. The principal investigator, responsible for data collection and therapist are also not aware of the type of consumer arbitration.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who have at least one line between two eyes and have vision should be 20/25 or better 2. age above 18 years 3. Patients with anisometropic or strabismic ambliotics Exclusion criteria: 1. Any eye disorder (cornea and retina, etc.) 2. Patients who do not cooperate with VEP 3. History of seizure 4. History of bipolar disorder 5. History of current or current use of SSRI or SNRI drugs 6. Patients who do not go to follow up 7. people under the age of 18

Intervention groups

Patients are randomly divided into two groups. One group receiving fluoxetine and the second group receiving placebo. The dose of fluoxetine is 20 mg per day, and each capsule is consumed every morning.

Main outcome variables

BCVA

General information

Reason for update

Typographical errors were corrected. Female sex had been erroneously entered as exclusion criteria that corrected. In inclusion criteria, the correct sentence was 'at least one line difference' that corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180316039110N1**
Registration date: **2018-06-05, 1397/03/15**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-15, 1403/02/26**
Update count: **1**

Registration date

2018-06-05, 1397/03/15

Registrant information

Name

Arash Mirmohammadsadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 1020

Email address

ammsadeghi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fluoxetine on visual acuity and VEP indices in amblyopia patients over 18 years of age

Public title

The Effect of Fluoxetine on Amblyopia Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who had at least one line difference between two eyes and have vision should be 20/25 or better age above 18 years Patients with anisometropic or strabismic amblyopia

Exclusion criteria:

Any eye disorder (cornea and retina, etc.) Patients who do not cooperate with VEP History of seizure History of bipolar disorder History of current or current use of SSRI or SNRI drugs Patients who do not go to follow up people under the age of 18

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation sequence was determined from a computer-generated, random-number table, assigning patients in to two groups

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind study of patients in the study, the type of drug are blind and do not know that fluoxetine or placebo consumption. The principal investigator, responsible for data collection and therapist are also not aware of the type of consumer arbitration.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

south Karegar St

City

tehran

Province

Tehran

Postal code

5561848331

Approval date

2016-09-11, 1395/06/21

Ethics committee reference number

IR.TUMS.FARABIH.REC.۱۳۹۵.۵۹۹

Health conditions studied

1

Description of health condition studied

Amblyopia

ICD-10 code

H53.033

ICD-10 code description

Strabismic amblyopia, bilateral

Primary outcomes

1

Description

BCVA

Timepoint

Every month for 90 days

Method of measurement

Based on the chart

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fluoxetine 20 mg

Category

Treatment - Drugs

2

Description

Control group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Farabi Hospital
Full name of responsible person
Arash Mir Mohammad Sadeghi
Street address
south Karegar St
City
Tehran
Province
Tehran
Postal code
5561848331
Phone
+98 912 792 7992
Email
ammsadeghi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahra'iyan
Street address
south Karegar St
City
Tehran
Province
Tehran
Postal code
5561848331
Phone
+98 21 8163 3698
Email
ammsadeghi@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Arash Mir Mohammad Sadeghi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
south Karegar St
City
Tehran
Province
Tehran
Postal code
5561848331
Phone
+98 912 792 7992
Email
ammsadeghi@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Alireza Mousavi
Position
resident
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
south Karegar St
City
Tehran
Province
Tehran
Postal code
5561848331
Phone
+98 66907846
Email
dr.mousavi@icloud.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mehdi aminizade
Position
resident

Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
south Karegar St
City
Tehran
Province
Tehran
Postal code
5561848331
Phone
+98 919 525 5337
Email
Mehdiaminizade@yahoo.com

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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable