Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Fluoxetine on treatment of amblyopia after critical period

Protocol summary

Summary

Amblyopia is the most common cause of visual impairment by prevalence about 1-5 % of the total population. As a Definition, amblyopia is decrease in visual acuity without any visible structural damage in eyes. Despite such definition of amblyopia, many studies demonstrate that Amblyopia cause damage to other visual functions too. If amblyopia is diagnosed and treated early in life, in most cases will lead to increase visual acuity to normal levels But if the treatment be postponed after 7 to 8 years of age (critical period) clinically is considered incurable due to lack of sufficient plasticity. Untreated amblyopia can cause vision loss and even blindness and can affects personal and professional abilities. Because of the increasing effect of Fluoxetine on neuronal plasticity, use of it in treatment of amblyopia was considered by the authors of this study. In this study, the effect of Fluoxetine in the treatment of amblyopia after the critical period, and various aspects of visual functionwas assessed , including contrast sensitivity, Stereopsis and impact of Fluoxetine on VEP latency at 15 and 60 minute. For this purpose, a total of 35 patients, age range 11 to 37 years on drug and placebo groups were categorized and Treatment was applied for 90 days. In both groups occlusion of healthy eye for 4-6 hours a day with eye activities such as reading , watching TV and video games was considered. Visual acuity, contrast sensitivity, stereopsis and VEP was assessed before and after treatment. In both groups visual acuity, contrast sensitivity and stereopsis improved after treatment. More VA improvement was seen in Fluoxetine group (0.24 log MAR) compare to placebo (0.12 log MAR). VEP latency for 60 minute, improved to normal levels in both groups, but only in Fluoxetine group for 15 minute.

General information

Acronym

Adult Amblyopia

IRCT registration information

IRCT registration number: **IRCT2016052428046N1**
Registration date: **2016-07-04, 1395/04/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-07-04, 1395/04/14

Registrant information

Name
Mohammad Hossein Sharif
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3252 0182
Email address
mhsharif2013@gmail.com

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-04-15, 1392/01/26

Expected recruitment end date

2013-09-17, 1392/06/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Fluoxetine on treatment of amblyopia after critical period

Public title

Effect of Fluoxetine on treatment of adult amblyopic

patients
Purpose
Treatment
Inclusion/Exclusion criteria
moderate amblyopic patients without any effective eye or systemic disorders
Age
From **11 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
karimkhan Zand street
City
Shiraz
Postal code
Approval date
2014-08-20, 1393/05/29
Ethics committee reference number
CT92-6471

Health conditions studied

1

Description of health condition studied
Amblyopia
ICD-10 code
H53
ICD-10 code description
Amblyopia

2

Description of health condition studied
amblyopia
ICD-10 code
H53
ICD-10 code description
Amblyopia

Primary outcomes

1

Description
Visual Acuity
Timepoint
monthly
Method of measurement
Snellen Chart

Secondary outcomes

1

Description
Contrast Sensitivity
Timepoint
Monthly
Method of measurement
CSV1000

2

Description
Stereopsis
Timepoint
Monthly
Method of measurement
Fly-so

3

Description
Visual Evoked Potential
Timepoint
Monthly
Method of measurement
Rplland Consolt

Intervention groups

1

Description
Fluoxetin, oral capsule, 0.50 mg/kg, onc a day, for 3 months
Category
Treatment - Drugs

2

Description

Placebo,oral capsule,once a day, for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poostchi Eye Research Center

Full name of responsible person

Dr Mohammad Reza Talebnejad

Street address

Setad sqr

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Karim Rastgar

Street address

Physiology Department, School of Medicine

City

Shiraz

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr karim Rastgar

Position

Associate Professor

Other areas of specialty/work

Street address

Physiology Department,School of Medicine,Setad Sqr.

City

Shiraz

Postal code

Phone

+98 71 3230 2026

Fax

Email

rastgark@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Poostchi Eye Research Center

Full name of responsible person

Dr Mohammad Reza Talebnejad

Position

Associate Professor

Other areas of specialty/work

Street address

Poostchi Eye Research Center, Setad Sqr.

City

Shiraz

Postal code

Phone

+98 71 3230 2830

Fax

talebmor@sums.ac.ir

Email

talebmor@sums.ac.ir; talebnejadmr@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Scinces

Full name of responsible person

Mohammad Hossein Sharif

Position

Student

Other areas of specialty/work

Street address

Physiology Department,School of Medicine,Setad Sqr.

City

Shiraz

Postal code

Phone

+98 71 3230 2026

Fax

Email

mhsharif2013@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty