

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 function was 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

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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
Fluoxetine, 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
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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