Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of fluoxetine on the treatment of accomodative spasm caused by anxiety

Protocol summary

Study aim
Effect of fluoxetine on the treatment of accommodative spasm caused by anxiety

Design
Randomized clinical trial with two intervention groups and two control groups, parallel groups, double blind

Settings and conduct
If patient is diagnosed with anxiety according to psychiatric clinical examinations, he/she is placed in the first group, and if patient does not have anxiety, he/she is placed in the second group. The patients of the first group are divided into two equal subgroups (intervention group and control group). The patients of the second group are also divided into two equal subgroups (intervention group and control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 15 to 35, having eye spasms with symptoms, bilateral accommodative spasm, no history of underlying diseases, absence of strabismus

Intervention groups
Two intervention groups: 1) Patients with anxiety are treated with fluoxetine 20 for 5 weeks, and in the fifth week, patients are treated with vision therapy under the supervision of an optometrist for three months. 2) Patients who do not suffer from anxiety and are given a suitable placebo similar to fluoxetine for 5 weeks, and in the fifth week, patients are treated with vision therapy under the supervision of an optometrist for three months. Two control groups: 1) Patients who suffer from anxiety and are only treated with fluoxetine 20 for 5 weeks. 2) Patients who do not suffer from anxiety and are given a suitable placebo similar to fluoxetine for 5 weeks

Main outcome variables
Dry and cyclo refractive errors, best corrected visual acuity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240617062160N1**
Registration date: **2024-06-29, 1403/04/09**
Registration timing: **prospective**

Last update: **2024-06-29, 1403/04/09**
Update count: **0**

Registration date
2024-06-29, 1403/04/09

Registrant information
Name
Mehrdad Sadeghi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 7754 2057
Email address
m.sadeghi1400@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-08-01, 1403/05/11
Expected recruitment end date
2025-05-01, 1404/02/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigating the effect of fluoxetine on the treatment of accomodative spasm caused by anxiety

Public title
The effectiveness of fluoxetine on the treatment of adaptive spasm caused by anxiety

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having eye spasms with symptoms Bilateral accommodative spasm (there should be conditions in both eyes and it should not be unilateral) No history of underlying diseases Absence of strabismus

Exclusion criteria:
Uncorrected hyperopia Having systemic diseases Having pathological anxiety Having eye diseases such as keratoconus, cataract, uveitis, retinal retinopathy, and all diseases that affect the quality of vision and visual system of the patient.

Age
From **15 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method is used to assign the participants to two groups of thirty-four people. In the block randomization method, we create blocks of four and randomly select a block of four for each four people. The block modes of four are as follows: AABB, ABAB, ABBA, BAAB, BABA, BBAA. We randomly choose one of the six quadruple block modes. For example, if the first mode is AABB, the first and second players are in group A, and the third and fourth players are in group B. We put them in the envelope and number each one from 1 to 64.

Blinding (investigator's opinion)
Double blinded

Blinding description
The main researcher is blinded to the selection and randomization of participants, and assigning groups will be done by another colleague. Treatment for the intervention group will be done on even days of the week and treatment for the control group will be done on odd days of the week, so the participants will be blinded to their treatment and group assignment. Data collection and analysis after the completion of the interventions will be done by another colleague who is blind to group assignment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Science

Street address
Arabi Ave., Daneshjoo Blvd., Velenjak

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2024-05-26, 1403/03/06

Ethics committee reference number
IR.SBMU.RETECH.REC.1403.081

Health conditions studied

1

Description of health condition studied
Accommodative spasm

ICD-10 code
H52.5

ICD-10 code description
Disorders of accommodation

Primary outcomes

1

Description
Dry refractive error

Timepoint
At the beginning of the study (before the start of the intervention), 5 weeks after the start of fluoxetine, and 3 months after the start of vision therapy

Method of measurement
Autorefractometer device

2

Description
Cyclo refractive error

Timepoint
At the beginning of the study (before the start of the intervention), 5 weeks after the start of fluoxetine, and 3 months after the start of vision therapy

Method of measurement

Autorefractometer device

3

Description
Best corrected visual acuity
Timepoint
At the beginning of the study (before the start of the intervention), 5 weeks after the start of fluoxetine, and 3 months after the start of vision therapy
Method of measurement
Glasses or contact lenses

Secondary outcomes

1

Description
Amplitude of accommodation
Timepoint
En At the beginning of the study (before the start of the intervention), 5 weeks after the start of fluoxetine, and 3 months after the start of vision therapy
Method of measurement
Dynamic retinoscopy

2

Description
Facility of accommodation
Timepoint
En At the beginning of the study (before the start of the intervention), 5 weeks after the start of fluoxetine, and 3 months after the start of vision therapy
Method of measurement
Dynamic retinoscopy

Intervention groups

1

Description
Intervention group: Patients with anxiety are treated with fluoxetine 20 for 5 weeks, and in the fifth week, patients are treated with vision therapy under the supervision of an optometrist for three months.
Category
Treatment - Other

2

Description
Patients who suffer from anxiety and are only treated with fluoxetine 20 for 5 weeks
Category
Treatment - Drugs

3

Description
Intervention group: Patients who do not suffer from anxiety and are given a suitable placebo similar to fluoxetine for 5 weeks, and in the fifth week, patients are treated with vision therapy under the supervision of an optometrist for three months.
Category
Treatment - Other

4

Description
Control group: Patients who do not suffer from anxiety and are given a suitable placebo similar to fluoxetine for 5 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation., Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mehrdad Sadeghiyan
Street address
Shahid Beheshti University of Medical Sciences, School of Rehabilitation, Damavand St, Emam Hossein Sq
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7756 1721
Email
sadeghiop88@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak.
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2243 9781
Email
zarghi@sbmu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mehrdad Sadeghi
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Optometry
Street address
Shahid Beheshti University of Medical Sciences, School of Rehabilitation, Damavand St., Emam Hossein Sq
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7756 1721
Email
sadeghiop88@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mehrdad Sadeghi
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Optometry
Street address
Shahid Beheshti University of Medical Sciences, School of Rehabilitation, Damavand St., Emam Hossein Sq
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7756 1721
Email
sadeghiop88@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mehrdad Sadeghi
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Optometry
Street address
Shahid Beheshti University of Medical Sciences, School of Rehabilitation, Damavand St., Emam Hossein Sq
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7756 1721
Email
sadeghiop88@yahoo.com

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