Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The effect of Atomoxetine on Cognitive Function of Inpatient and Outpatient Multiple Sclerosis

Protocol summary

Study aim

1.Determining the frequency of cognitive disorders in the study population in the group of Atomoxetine and Placebo 2.Comparison of changes in cognitive impairment before and after drug administration between Placebo and Atomoxetine

Design

Clinical trial with control group,double blind, randomized, phase 3 ,with a parallel group design of 52 patients. For randomization, a randomized block method with 4 blocks was used

Settings and conduct

.Patients referred to outpatient or inpatient clinics of Golestan Hospital in Ahvaz are selected after reviewing the inclusion and exclusion criteria. Initially, McFims test patients are taken in a double-blind study. The number of each patient is placed on the drug package based on the software randomization list. Also, two placebo and Atomoxetine drugs are packaged in such a way that the patient does not know the name of the drug and is given to patients by a nurse not related to the research. In such a way that the attending physician is not aware of the medication provided to each patient.Group A, which consists of 26 patients selected by an uninformed person, will be treated with Atomoxetine for three months, and group B, which includes 26 patients, will be treated by an uninformed person. Will be selected and treated with placebo. At the beginning and end of 3 months, McFims test is performed for patients.

Participants/Inclusion and exclusion criteria

Entry requirements; Age between 18 and 55 years; Testable measurable cognitive impairment McFims attributed to multiple sclerosis; Diagnosis of multiple sclerosis based on McDonald's criteria No entry conditions; Continuous use of stimulants; Contraindications to the use of Atomoxetine

Intervention groups

Group A will be treated with Atomoxetine and group B will be treated with Placebo

Main outcome variables

Language; executive function; processing speed ; functional memory; new learning power

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210715051901N1**
Registration date: **2021-09-07, 1400/06/16**
Registration timing: **prospective**

Last update: **2021-09-07, 1400/06/16**
Update count: **0**

Registration date

2021-09-07, 1400/06/16

Registrant information

Name

Effat Amouzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3522 7599

Email address

effatamouzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Atomoxetine on Cognitive Function of Inpatient and Outpatient Multiple Sclerosis

Public title

The effect of Atomoxetine on Cognitive Function of Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Multiple Sclerosis based on McDonald's criteria Age between 18 to 55 years Testable Measurable Cognitive impairment (MACFIMS) attributed to Multiple Sclerosis

Exclusion criteria:

Continued use of Stimulant Clinical relapse of Multiple Sclerosis with in 60 days of screening Changes in the treatment of Multiple Sclerosis within 90 days of screening Existence of any underlying factor and disease that causes dementia and cognitive impairment Proof of moderate to severe depression with a Beck's test Contraindications to the use of Atomoxetine Confirmation of cognitive impairment related to Multiple Sclerosis with McFimes test

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized controlled clinical trial. In this study, patients will be assigned to each of the treatment groups by a randomized block method using 4 blocks Which are selected from patients referring to the clinic or outpatient or inpatient clinics of Golestan Hospital in Ahvaz after reviewing the inclusion and exclusion criteria Exits are selected. At the beginning of the study, patients are tested with McFimes. Randomization or random assignment of patients to each treatment group will be done by randomized block method using 4 blocks by winpepi 11.4 software. Subjects were randomly divided into two groups based on the method of quadruple random blocks. The study is a double-blind study in the sense that the patient and the medical staff are unaware of the type of treatment assigned to each person. The number of each patient is placed on the drug package based on the software randomization list. Also, two placebo and Atomoxetine drugs are packaged in such a way that the patient does not know the name of the drug and is given to patients by a nurse not related to the research. In such a way that the attending physician is not aware of the medication provided to each patient. The Beck test is used to check for depression, and people who score 9 on this test are excluded from the study. Patients who will not be able to continue their study due to intolerance to Atomoxetine will be excluded from the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is a double-blind study in the sense that the patient and the medical staff are unaware of the type of treatment assigned to each person. In this study, patients will be assigned to each treatment group using a randomized block method using 4 blocks. The number of each patient is placed on the drug package based on the software randomization list. Also, two placebo and Atomoxetine drugs are packaged in such a way that the patient does not know the name of the drug and is given to patients by a nurse not related to the research. In such a way that the attending physician is not aware of the medication provided to each patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

unit 11, Mohammad 5 Residential complex, Between Eghbal st and Nosrat st, Isfahan Ave, Golestan District

City

Ahvaz

Province

Khouzestan

Postal code

6136913847

Approval date

2021-02-25, 1399/12/07

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.148

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G37.9
ICD-10 code description
Demyelinating disease of central nervous system, unspecified

Primary outcomes

1

Description
Cognitive Disorder Score in MacFims Questionnaire
Timepoint
Perform MacFims test at the beginning of the study and three months after the start of the study
Method of measurement
MacFims Questionnaire

Secondary outcomes

1

Description
Accompanying depression score
Timepoint
At the beginning of the study and 3 months later
Method of measurement
Beck Questionnaire

Intervention groups

1

Description
Intervention group: The intervention group consisted of 26 patients who will be treated with Atomoxetine capsules at a dose of 40 mg daily for 2 weeks and then increased to 80 mg daily to 40 mg twice daily for It will take three months
Category
Treatment - Drugs

2

Description
The control group consisted of 26 patients who will be treated with placebo-like Atomoxetine capsules once daily for 2 weeks and then increased twice daily for three months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Ehsan Mohammadian negad
Street address
Neurology Department, next to Farvardin Boulevard, Golestan Hospital, Golestan Alley
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6136835685
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effatamouzadeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mahdi Ahmadimoghadam
Street address
Ground Floor ,Vice Chancellor for Research and Technology Ahvaz Jundishapur University of Medical Sciences and Health Services, University City
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6136913847
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itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Effat Amouzadeh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

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unit 11, Mohammad 5 Residential complex, Between Eghbal st and Nosrat st, Isfahan Ave, Golestan District

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
Access period starts 3 months after the results are published

To whom data/document is available
It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
The use of documentation is permitted for non academic neurologists and other specialist physicians

From where data/document is obtainable
Effat Amouzadeh, contact number 09106530322, email effatamouzadeh@gmail.com, address of residence unit 11, Mohammad 5 Residential complex, Between Eghbal st and Nosrat st, Isfahan Ave, Golestan District, Postal Code 6136913847

What processes are involved for a request to access data/document
Sending an email or letter to Effat Amouzadeh's mailing address, will be responsive within a week

Comments