

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation the effects of atomoxetine on the improvement of cognitive impairment in Behcet's disease patients

Protocol summary

Study aim

Evaluation the effects of atomoxetine on the improvement of cognitive impairment in Behcet's disease patients

Design

parallel group, double blind, randomized controlled trial

Settings and conduct

In this double blind, randomized placebo controlled clinical trial, 40 eligible individual, at Rheumatology clinic of Shariati hospital (Tehran University of Medical Sciences), will be randomized between two groups. In the intervention group, Atomoxetine capsule (Amin pharmaceutical company) will be administered 40mg/day. After 3 days will be increased to 40mg, twice a day and then continued for 10 weeks. In the control group, Patients take placebo which is completely the same with Atomoxetine capsule for 10 weeks. Dosing will be the same with intervention group too. Before and after Atomoxetine and placebo administration, participant's cognitive function will be assessed by following tests: Forward digit span, Backward digit span, Trail making A, Trail making B, Verbal fluency; and results will be compared. Blinding of participants, investigators and outcome assessors will be done.

Participants/Inclusion and exclusion criteria

inclusion criteria: Individuals diagnosed with Behcet's disease based on international criteria for Behcet's disease (ICBD) Presence of cognitive impairment
exclusion criteria: History of cognitive impairment before being affected by Behcet's disease Substance use

Intervention groups

Intervention group: initially, Atomoxetine capsule (Amin pharmaceutical company) will be administered 40mg/day. After 3 days will be increased to 40mg, twice a day and then continued for 10 weeks. Control group: Patients take placebo which is completely the same with Atomoxetine capsule for 10 weeks. Dosing will be the same with intervention group too.

Main outcome variables

change in following test scores: Forward digit span
Backward digit span Trail making A Trail making B Verbal fluency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211206053288N1**

Registration date: **2022-02-20, 1400/12/01**

Registration timing: **prospective**

Last update: **2022-02-20, 1400/12/01**

Update count: **0**

Registration date

2022-02-20, 1400/12/01

Registrant information

Name

malekfarhad malek

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 9151

Email address

malekmf@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2023-12-25, 1402/10/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the effects of atomoxetine on the improvement of cognitive impairment in Behcet's disease patients

Public title
Atomoxetine for cognitive impairment in Behcet's disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Individuals diagnosed with Behcet's disease according to ICD (International Criteria for Behcet's Disease) criteria Presence of cognitive impairment detected by following tests: Forward digit span, Backward digit span, Trail making A, Trail making B, Verbal fluency
Exclusion criteria:
History of cognitive impairment before affected by Behcet's disease Substance use History of adverse reactions to Atomoxetine

Age
From **17 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple method with Computer-generated randomization schedule with allocation concealment

Blinding (investigator's opinion)
Double blinded

Blinding description
participants investigators healthcare providers data collectors outcome assessors

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tehran University of Medical Sciences
Street address
Room 605, 6th Floor, Central organization of Tehran University of Medical Sciences, Corner of Qods street, Keshavarz boulevard, Tehran, Irand
City
Tehran
Province
Tehran
Postal code
1416634793
Approval date
2021-07-18, 1400/04/27
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.462

Health conditions studied

1

Description of health condition studied
Behcet's disease
ICD-10 code
M35.2
ICD-10 code description
Behcet's disease

2

Description of health condition studied
Cognitive impairment
ICD-10 code
G31.84
ICD-10 code description
Mild cognitive impairment, so stated

Primary outcomes

1

Description
score of following cognitive tests: Forward digit span, Backward digit span, Trail making A, Trail making B, Verbal fluency
Timepoint
before intervention and 10 weeks after intervention
Method of measurement
cognitive tests: Forward digit span, Backward digit span, Trail making A, Trail making B, Verbal fluency

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: initially, Atomoxetine capsule (Amin pharmaceutical company) will be administered 40mg/day. After 3 days will be increased to 40mg, twice a day and then continued for 10 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients take placebo which is completely the same with Atomoxetine capsule for 10 weeks. Dosing will be the same with intervention group too.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Malekfarhad Malek

Street address

Shariati hospital, North Kargar street, Tehran, Iran

City

Tehran

Province

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Postal code

1411713135

Phone

+98 21 8490 1000

Email

shariatihosp@tums.ac.ir

Web page address

http://shariati.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

6th floor of central organization of Tehran University of Medical Sciences, Corner of Qods street, Keshavarz boulevard

City

Tehran

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Postal code

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Phone

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Email

vcr@tums.ac.ir

Web page address

https://vcr.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

Malekfarhad Malek

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Rouzbeh hospital, south Kargar St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Malekfarhad Malek

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Malekfarhad Malek

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

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City