Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 ICBD (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
Tehran
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
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
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.
City
Tehran
Province
Tehran
Postal code
1333715914
Phone
+98 21 5541 9151
Fax
Email
malekmf@sina.tums.ac.ir

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
Psychiatrics
Street address
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City
Tehran
Province
Tehran
Postal code
1333715914
Phone
+98 21 5541 9151
Fax
Email
malekmf@sina.tums.ac.ir

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
Rouzbeh hospital, south Kargar St.
City
Tehran
Province
Tehran
Postal code
1333715914
Phone
+98 21 5541 9151
Fax
Email
malekmf@sina.tums.ac.ir

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