Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The Effect of Atomoxetine on Cognitive Symptoms in Schizophrenia Patients

Protocol summary

Study aim
The Effect of Atomoxetine on Cognitive Symptoms in Schizophrenia Patients
Design
A controlled clinical trial with parallel, double-blind, randomized groups was designed on 40 patients with schizophrenia based on case number (even or odd).
Settings and conduct
In this clinical trial, 40 patients with schizophrenia referred to a psychiatric clinic will be randomly divided into two equal groups of atomoxetine and placebo. In the atomoxetine group, patients are given 40 mg of atomoxetine daily for 8 weeks, and in the placebo group, similar tablets in terms of size and color of atomoxetine are prepared from starch and given to patients daily for 8 weeks.
Participants/Inclusion and exclusion criteria
Inclusion criteria: schizophrenia, score of 61 or more on the panss questionnaire; Exclusion criteria: Other neurological disorders, atomoxetine hypersensitivity, complications including angioedema, liver failure, aggression, psychosis, patients receiving ECT in the last 6 weeks, patients taking the antipsychotic drug clozapine
Intervention groups
In the atomoxetine group, patients are given 40 mg of atomoxetine daily for 8 weeks, and in the placebo group, similar tablets in terms of size and color of atomoxetine are prepared from starch and given to patients daily for 8 weeks.
Main outcome variables
Wechsler Short-Term Memory Test

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211219053452N1**
Registration date: **2022-06-25, 1401/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-25, 1401/04/04**
Update count: **0**
Registration date
2022-06-25, 1401/04/04

Registrant information
Name
Fatemeh Yousefi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 86 3367 7022
Email address
fatemehyy75@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-21, 1401/02/01
Expected recruitment end date
2022-07-23, 1401/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Atomoxetine on Cognitive Symptoms in Schizophrenia Patients

Public title
The Effect of Atomoxetine on Cognitive Symptoms in Schizophrenia Patients
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Schizophrenia Get a score of 61 or higher on the panss questionnaire

Exclusion criteria:

Simultaneous presence of other neurological disorders Any allergy to atomoxetine Patients who have received ECT in the last 6 weeks

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple random method based on the patients' record number (odd and even) will be divided into two completely equal groups of atomoxetine and placebo groups (neutral and inert substances such as starch) that have no pharmacological effect on the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and the patient are both unaware of which group they belong to, and the patients, in pairs and individually, are completely equal to the two groups of atomoxetine and the placebo group (a neutral and inert substance like starch in appearance similar to atomoxetine) that has no pharmacological effect on They do not affect the patient and will be divided on the assumption that the drug has a pharmacological or physiological effect on the patient's condition.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Alam al-Huda St., Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2022-04-13, 1401/01/24

Ethics committee reference number

IR.ARAKMU.REC.1401.002

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Wechsler Short-Term Memory Test

Timepoint

Before the intervention and after 8 weeks of treatment

Method of measurement

Wechsler test

Secondary outcomes

1

Description

Short-term memory expansive score, direct visual memory, reverse visual memory, direct auditory memory, auditory reverse memory

Timepoint

Before the intervention and after 8 weeks of treatment

Method of measurement

How to measure short-term memory, direct visual memory, reverse visual memory, direct auditory memory, auditory reverse memory using Wechsler test

Intervention groups

1

Description

Intervention group: Patients are given 40 mg of atomoxetine daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Similar tablets in terms of size and color of atomoxetine are prepared from starch and will be given to patients daily for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric Clinic of Amirkabir Hospital, Arak

Full name of responsible person

Fatemeh Yousefi

Street address

Hepco St. - Imam Hossein St. - Golzar 11

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3818133150

Phone

+98 86 3367 7022

Email

Fatemehyy75@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

Street address

Arak - Basij Square - Arak University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Yousefi

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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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 unidentifiable individuals

When the data will become available and for how long
Start the access period immediately after printing the results

To whom data/document is available
Study data will be available to researchers working at academic and scientific institutes

Under which criteria data/document could be used
Any analysis on unidentifiable individual data is allowed.

From where data/document is obtainable
Send your request via email

What processes are involved for a request to access data/document
Documents or data files will be sent to the applicant after receiving the request

Comments