

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Study of the effect of Atomoxetine in comparison with placebo on cognitive symptoms in patients with schizophrenia

#### Protocol summary

##### Study aim

Study of effect of Atomoxetine on cognitive symptoms in patients with schizophrenia

##### Design

42 schizophrenic patients were divided into two groups of intervention and control through block randomization. Randomized, triple-blind, placebo-controlled, single-center, phase II trial.

##### Settings and conduct

The study was conducted at Clinic of Psychiatry of the University Hospital Ibn.e.Sina and Dr. Hejazi, Mashhad. patient was diagnosed with schizophrenia aged 18-60 years are evaluated based on the inclusion and exclusion criteria and only patients who meet these criteria are selected. as a triple blind (the patient, elevator and physician and data analyses will all be blind and the medication and placebo in envelopes A and B will be given by the nurse).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Use Antipsychotic Generation 2 Drug - Lack of dementia- Not taking other medicines (except anticholinergics and benzodiazepines)- No pregnancy or breastfeeding- There is no recent history of drugs (except nicotine)- schizophrenic patients during partial recovery. Exclusion criteria: Drug side effects including: abdominal discomfort, loss of appetite resulting in weight loss, dizziness, irritability and mood swings- Occurrence of drug interactions with patient medications.

##### Intervention groups

Intervention group: Patients are given 40 mg of atomoxetine daily for 4 weeks and then 80 mg for another 4 weeks. Control group: Control group is given placebo according to the same protocol. Placebo is manufactured and prepared by the Mashhad School of Pharmacy.

##### Main outcome variables

cognitive function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101130005280N31**

Registration date: **2019-12-21, 1398/09/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-21, 1398/09/30**

Update count: **0**

##### Registration date

2019-12-21, 1398/09/30

##### Registrant information

##### Name

Raheleh Nejati

##### Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3711 2540

##### Email address

nejatir2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-02-19, 1398/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Study of the effect of Atomoxetine in comparison with placebo on cognitive symptoms in patients with schizophrenia

## Public title

Study of the effect of Atomoxetine on cognitive symptoms in patients with schizophrenia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

2nd Generation Antipsychotic Drug use Lack of dementia Not taking other medicines (except anticholinergics and benzodiazepines) No pregnancy or breastfeeding There is no recent history of drugs (except nicotine) schizophrenic patients during partial recovery

### Exclusion criteria:

Drug side effects including: abdominal discomfort, loss of appetite resulting in weight loss, dizziness, irritability and mood swings Occurrence of drug interactions with patient medications

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **42**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block Randomization We can create a block to assign sample numbers equally to each group. If block size is two, we can make two possible sequences of AB and BA. based on arrangement allocated participants to a treatment and control groups with sealed envelope

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Building Ghoreshi, Central Organization of Mashhad University of Medical Sciences, Daneshgah Avenue, Mashhad, Iran.

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

1394491388

#### Approval date

2019-04-16, 1398/01/27

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.170

## Health conditions studied

### 1

#### Description of health condition studied

schizophrenia

#### ICD-10 code

F00-F98

#### ICD-10 code description

اختلالات رفتاری و روانی

## Primary outcomes

### 1

#### Description

Cognitive function

#### Timepoint

Before intervention, end of first and second

#### Method of measurement

PANSS.Wisconsin, Stroop, Digit Span Questionier

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients are given 40 mg of atomoxetine is given daily by Tadbir Kala Jam Pharmaceutical Company for 4 weeks and then 80 mg for another 4 weeks.

#### Category

Treatment - Drugs

**2**

**Description**

Control group is given placebo according to the same protocol. Placebo is manufactured and prepared by the Mashhad School of Pharmacy

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ibn.e.Sina and Dr. Hejazi Psychiatry Hospital

**Full name of responsible person**

Dr Fatemeh Behdani

**Street address**

Ibn-e-Sina Hospita, Bu-Ali Sq., Amel Blvd., Mashhad.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

919583134

**Phone**

+98 51 3711 2701

**Email**

behdanif@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Building Ghoreshi, Central Organization of Mashhad University of Medical Sciences, Daneshgah Avenue, Mashhad, Iran.

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tafaghodim@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Fatemeh Behdani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available