Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Inclucion 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 automoxetine 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 Scinces, Ibn-e- Sina Psychiatric Hospital

Country
Iran (Islamic Republic of)

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+98 51 3711 2540

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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 automoxetine 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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Building Ghoreshi, Central Organization of Mashhad University of Medical Sciences, Daneshgah Avenue, Mashhad, Iran.
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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
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