

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The evaluation of atypical antipsychotic augmentation with Atomoxetine in the reduction of negative symptoms in patients with Schizophrenia

Protocol summary

Study aim

The evaluation of atypical antipsychotic augmentation with Atomoxetine in the reduction of negative symptoms in Patients with Schizophrenia

Design

The study is a randomized double blind clinical trial with community based and pragmatic control group, with parallel groups design. There will be 30 patients in each group. Randomization is done by permutation block method. Patients and evaluators do not know the type of medication receiving by each group.

Settings and conduct

In this double-blind clinical trial, 60 patients will enter the study. The patients will be selected from the patients who will be admitted to the psychiatric ward or referred to the psychiatric clinic of the Ahvaz Golestan Hospital with schizophrenia diagnosis and their disease will be confirmed by a psychiatrist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Detection of schizophrenia based on the diagnosis of a psychiatrist who is a faculty member and an psychiatry assistant through a clinical interview based on DSM-5; Bold negative symptoms (PANSS negative symptom sub-scale score more than 15); Not having liver disease; Become as a schizophrenia patients for more than 1 year; Age range between 18 and 70 years. Exclusion criteria: Presence of Depression based on DSM-5 Clinical Interview; Presence of Bipolar disorder; Pregnant or lactating woman; Substance abuse during the last month; patients suffering from Attention Deficit Hyperactivity Disorder (ADHD).

Intervention groups

Intervention group: A group of 30 patients will receive atomoxetine 40 mg daily in the first week and then 80 mg daily in the following weeks until the 8th week. The effect of the medication on the negative symptoms from the perspective of negative signs and overall scores will be compared with the PANSS scale at the onset of the treatment, and the 4th and 8th weeks. Control group:

This group will receive placebo tablets which will be similar to atomeboxin in shape, color, odor, and taste.

Main outcome variables

lack of social interest; Frivolity; Anhedonia; loss of motivation,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100520003979N9**

Registration date: **2018-10-19, 1397/07/27**

Registration timing: **prospective**

Last update: **2018-10-19, 1397/07/27**

Update count: **0**

Registration date

2018-10-19, 1397/07/27

Registrant information

Name

Forugh Riahi

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3038

Email address

riahi-f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of atypical antipsychotic augmentation with Atomoxetine in the reduction of negative symptoms in patients with Schizophrenia

Public title

Evaluation the effect of atypical antipsychotic augmentation with Atomoxetine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Detection of schizophrenia based on the diagnosis of a faculty psychiatrist and an psychiatrist assistant with a clinical interview based on DSM-5 Bold negative symptoms(PANSS negative symptom sub-scale score more than 15) Not having liver disease Suffering from the disease for more than a year Age between 18 and 70 years.

Exclusion criteria:

Presence of Depression based on DSM-5 Clinical Interview Presence of Bipolar disorder Pregnant or lactating woman Substance abuse during the last month patients suffering from Attention Deficit Hyperactivity Disorder (ADHD)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the method of the permutation blocks of size 4, individuals are randomly divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The placebo is similar to atmoxtein in shape, color, smell and taste and will be available at the Faculty of Pharmacy, Ahwaz University of Medical Sciences. The medication will be prescribed by the assistants and given to the patients by the nurses at psychiatric ward. The project executor is not aware of the prescriptions in each group. Also, the patient is not aware of the type of medicine takes.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd, Ahvaz, Khoozestan

City

Ahvaz

Province

Khoozestan

Postal code

6135715794

Approval date

2018-09-22, 1397/06/31

Ethics committee reference number

IR.AJUMS.REC.1397.416

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes**1****Description**

Lack of social interest

Timepoint

At the beginning of the treatment and at 4th and 8th weeks

Method of measurement

PANSS scale

2**Description**

Frivolity

Timepoint

At the beginning of the treatment and at 4th and 8th weeks

Method of measurement

PANSS scale

3

Description

Anhedonia

Timepoint

At the beginning of the treatment and at 4th and 8th weeks

Method of measurement

PANSS scale

4

Description

Loss of motivation

Timepoint

At the beginning of the treatment and at 4th and 8th weeks

Method of measurement

PANSS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Atomoxetine is given 40 mg daily in the first week and 80 mg daily in the following weeks until 8 weeks. The effect of the medication on the negative symptoms in the two groups is compared with the PANSS scale at the start of the treatment and the weeks 4th and 8th for negative signs and the overall score scales.

Category

Treatment - Drugs

2

Description

Control group: This group will receive placebo which is similar to Atomoxetin in shape, color, smell, and taste.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Adolecent and child Psychiatry Clinic, Golestan Hospital

Full name of responsible person

Forough Riahi

Street address

Ahvaz Golestan Hospital, Golestan Blvd,Ahvaz

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Riahi13@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Forough Riahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Erfanifar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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

No more 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