

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of added buspiron to atypical antipsychotic drugs in the treatment of negative symptoms in patients with schizophrenia

Protocol summary

Summary

The aim of this study is to evaluate the effectiveness of second-generation antipsychotics addition of buspiron to treat the negative symptoms of schizophrenia patients. 40 patients with schizophrenia are divided randomly into two treatment groups, each one 20 patients. Present study is double blinded with Trial phase 2 and 3. Patients with schizophrenia and a score more than 15 subtypes in negative symptoms are in the study and if they had a history of sensitivity to antipsychotics or buspiron or they are bipolar disorders, then excluded. The intervention group received 40 mg buspiron and second generation antipsychotic risperidone equivalent of 2-6 mg of risperidone and the case group receive 40 mg placebo with the second generation of 2-6 mg of risperidone. Patients will be evaluated at baseline and 3th and 6th week about negative symptoms of schizophrenia and the general scale PANSS. This test have been designed to evaluate the dimension and phenomenological aspects of schizophrenia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010431626N2**

Registration date: **2017-03-21, 1396/01/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-21, 1396/01/01

Registrant information

Name

Hatam Boostani

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3374 3038

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of added buspiron to atypical antipsychotic drugs in the treatment of negative symptoms in patients with schizophrenia

Public title

The effect of added buspiron to atypical antipsychotic drugs in the treatment of negative symptoms in patients with schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age between 18 and 65 years old; Having schizophrenia according to DSM-VI-TR criteria; Bold negative symptoms(PANSS negative symptom sub-scale score more than 15); Disease duration of more

than six months Exclusion criteria: Bipolar disorders; Depression and other psychiatric disorders; Chronic medical conditions (liver, kidney and heart); A history of sensitivity to antipsychotics or buspirone; A history of failure to respond to treatment with adequate doses of antipsychotic medication; History of seizures; Pregnancy; Breastfeeding; Any disruption in the electrocardiogram; Simultaneous treatment with other drugs and active suicidal thoughts

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization was done by random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz

City

Ahvaz

Postal code

Approval date

2016-07-02, 1395/04/12

Ethics committee reference number

IR.AJUMS.REC.1395.199

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

schizophrenia

Primary outcomes

1

Description

Negative symptoms

Timepoint

Before intervention, Three and six weeks after intervention

Method of measurement

PANSS questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receive 40 mg buspirone and the second generation antipsychotic equivalent of 2-6 mg of risperidon.

Category

Treatment - Drugs

2

Description

Control group: patients with schizophrenia receive 40mg placebo with the second generation of 2-6 mg of risperidone. Placebo pill will be like buspirone about the shape, color, smell and size.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan hospital

Full name of responsible person

Hatam Boostani

Street address

Ahvaz Golestan hospital, Golestan Blvd, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

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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

Vice chancellor for research Ahvaz Jundishapur
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty