Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 buspirone 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 buspirone or they are bipolar disorders, then excluded. The intervention group received 40 mg buspirone and second generation antipsychotic risperidone equivalent of 2-6 mg of risperidon 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)

Phone

+98 61 3374 3038

Email address

tabibi.y@ajums.ac.ir

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
Hatam Boostani

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz

City
Ahvaz

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
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Hatam Boostani

Position
Assistant Professor

Other areas of specialty/work

Street address
Department of Psychiatry, Golestan hospital, Golestan Blvd, Ahvaz

City
Ahvaz

Postal code

Phone
+98 616133743038

Fax

Email
boostani-h@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Hata, Boostani

Position
Assistant Professor

Other areas of specialty/work

Street address
Department of Psychiatry,Golestan Hospital,Golestan Blvd,Ahvaz

City
Ahvaz

Postal code

Phone
+98 616133743038

Fax

Email
boostani_h@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Naghme Malek poor

Position
Assistant

Other areas of specialty/work

Street address
Ahvaz Golestan hospital, Golestan Blvd, Ahvaz

City
Ahvaz

Postal code

Phone
+98 616133743038

Fax

Email
n-malekpoor24@yahoo.com

Web page address

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