Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Buspirone added to Typical Antipsychotics on Positive and Negative symptoms in schizophrenia (a double blind, placebo controlled, randomized trial)

Protocol summary

Summary

The object of this randomized, placebo controlled, double blind study is to test the hypothesis that the addition of Buspirone would improve psychopathology in subjects with Schizophrenia treated with Typical Antipsychotics. 50 patients with ages between 18-65 years who have no other medical or psychiatric conditions with chronic DSMIV-TR diagnosed Schizophrenia will receive Typical Antipsychotics combined with either placebo (N=25) or 30 mg/day of Buspirone (N=25) for 6 weeks. Efficacy will be defined as the change from baseline to endpoint in score on the Possitive and Negative Syndrom Scale(PANSS). Side effects will be also evaluated using checklist and Extrapyramidal Symptom Rating Scale. PANSS, SAS, GAF, MMSE Scales and side effects will be evaluated at baseline,2,4 and 6 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106026691N1**
Registration date: **2012-09-17, 1391/06/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-09-17, 1391/06/27

Registrant information

Name
Fatemeh Sheikhmoonesi
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health Service

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Buspirone added to Typical Antipsychotics on Positive and Negative symptoms in schizophrenia (a double blind, placebo controlled, randomized trial)

Public title

Effect of Buspirone added to Typical Antipsychotics on Positive and Negative symptoms in schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Age between 18-65; Diagnosis of Schizophrenia based on DSMIV-TR; Chronic Schizophrenia(over 2 years); Ongoing treatment with Typical Antipsychotics. Exclusion criteria:Allergic to Buspirone; Any chronic medical problem; Substance dependency; Any other Psychiatric Disorder in Axis I or II; Pregnancy or Breast feeding.

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran University of Medical Sciences
Street address
Central building of Mazandaran University of Medical Scienses and Health Service, Daneshgah Blvd, Emam Square
City
Sari
Postal code
48154
Approval date
2011-05-31, 1390/03/10
Ethics committee reference number
1353

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Severity of schizophrenia
Timepoint
Baseline and weeks 2-4-6 after begining of treatment
Method of measurement
Positive and Negative Syndrome Scale(PANSS)

Secondary outcomes

1

Description
Headache
Timepoint
Baseline and weeks 2,4,6 after begining of treatment
Method of measurement
Check list of adverse effects

2

Description
Nausea
Timepoint
Baseline and weeks 2-4-6 after begining of treatment
Method of measurement
Checklist of adverse effects

3

Description
Palpitation
Timepoint
Baseline and weeks 2-4-6 after begining of treatment
Method of measurement
Checklist of adverse effects

Intervention groups

1

Description
Typical Antipsychotics combined with Tablet Buspirone(30 mg/day) as intervention group for 6 weeks
Category
Treatment - Drugs

2

Description
Typical Antipsychotics combined with Tablets placebo as control group for 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Zare Psychiatry Hospital

Full name of responsible person

Dr Fatemeh Sheikhmoonesi

Street address

Psychiatric Department, Zare Psychiatry Hospital, Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmadali Enayati

Street address

Vice Chancellor for Research and Technology, Building N.2, Moallem Square, Moallem Street

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Fatemeh Sheikhmoonesi

Position

Assistant Prof. of Psychiatry, Psychiatrist

Other areas of specialty/work

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Person responsible for scientific inquiries

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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