

# 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 Positive and Negative Syndrome 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1328 5109

##### Email address

fmoonesi@mazums.ac.ir

##### 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 Sciences 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 beginning of treatment

#### Method of measurement

Positive and Negative Syndrome Scale(PANSS)

## Secondary outcomes

### 1

#### Description

Headache

#### Timepoint

Baseline and weeks 2,4,6 after beginning of treatment

#### Method of measurement

Check list of adverse effects

### 2

#### Description

Nausea

#### Timepoint

Baseline and weeks 2-4-6 after beginning of treatment

#### Method of measurement

Checklist of adverse effects

### 3

#### Description

Palpitation

#### Timepoint

Baseline and weeks 2-4-6 after beginning of treatment

#### Method of measurement

Checklist of adverse effects

## Intervention groups

### 1

#### Description

Typical Antipsychotics combined with Tablet Bupirone(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**  
**Street address**  
Zare Psychiatry Hospital  
**City**  
Sari  
**Postal code**  
4815466848  
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**Email**

fmoonesi@mazums.ac.ir  
**Web page address**

## Person responsible for scientific 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  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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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*