

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Efficacy of ondansetron augmentation in negative sign of Schizophrenia

Protocol summary

Summary

The purpose of this study is to assess the efficacy of ondansetron, a 5-HT₃ receptor antagonist as an adjuvant agent in the treatment of chronic schizophrenia in particular for negative symptoms. This investigation is a 12-week, double blind study of parallel groups of patients with stable chronic schizophrenia. 44 patients are recruited from inpatient and outpatient departments. All participants meet Diagnostic and Statistical Manual of Mental Disorders Fourth Edition, Text Revision (DSM-IV-TR) criteria for schizophrenia. To be eligible, patients are required to have treated with a stable dose of risperidone as their primary antipsychotic treatment for a minimum period of 8 weeks. The subjects are randomized to receive ondansetron (8 mg/day) or the placebo in addition to risperidone. Clinical psychopathology is assessed with Positive and Negative Syndrome Scale (PANSS). Cognition is measured by a Wechsler memory scale. Patients are assessed at baseline and after 4, and 8 weeks after the medication started. The PANSS scores and cognitive performance are used as the outcome measures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112125280N7**

Registration date: **2012-04-17, 1391/01/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-17, 1391/01/29

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of ondansetron augmentation in negative sign of Schizophrenia

Public title

The Efficacy of ondansetron augmentation in negative sign of Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients who have been treated with a stable dose of risperidone as their primary antipsychotic treatment for a minimum period of 8 weeks before entry into the study. Exclusion criteria: Patients who had any medical diagnoses (including ECG conduction

abnormalities, neurological disorder, or an active seizure) or were receiving medications that may have affected cognitive performance; Subjects who met the criteria for a DSM IV diagnosis of alcohol or substance abuse (other than for nicotine) within the last month or the criteria for DSM-IV alcohol or substance dependence (other than for nicotine) within the last 6 months; Pregnant or lactating women and those of reproductive age without adequate contraception; psychotropic medications were not allowed for the duration of the study: anticholinergics, sedating antihistaminic, antidepressants, mood stabilizers, or a second antipsychotic (as adjuvant therapy).

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 44

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**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Daneshgah Street, Ghoreishi Building

City

Mashhad

Postal code**Approval date**

2010-06-15, 1389/03/25

Ethics committee reference number

89641

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

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

negative symptom

Timepoint

base line, weeks 4,8

Method of measurement

PANSS

Secondary outcomes

empty

Intervention groups**1****Description**

Patients are required to have treated with a stable dose of risperidone (4-6mg/day) as their primary antipsychotic treatment and receive ondansetron (4-8 mg/day) for a minimum period of 8 weeks.

Category

Treatment - Drugs

2**Description**

The control group receive the placebo in addition to risperidone (4-6 mg/day).

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ibn-e-Sina psychiatric Hospital

Full name of responsible person

Faezeh Soltan Ahmadi

Street address

Ebne Sina psychiatric Hospital, Horre ameli avenue, Boo Ali square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Marjan Ardakanian

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Ghoreishi Building, Daneshgah Street

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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

Mashhad 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**

Ibn-e-sina Hospital, Mashhad University of Medical Sciences

Full name of responsible person

Dr Soozan Soluti

Position

resident

Other areas of specialty/work**Street address**

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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