Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Scinces, Ibn-e- Sina Psychiatric Hospital

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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 Scinces
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
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Marjan Ardakanian
Street address
Ghoreishi Building, Daneshgah Street
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Mashhad
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
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Person responsible for updating data

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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