Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Study of the efficacy and safety of ondansetron as an adjuvant to antipsychotics in patients with chronic schizophrenia: A randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

Assessment of the efficacy and safety of ondansetron as an adjuvant to antipsychotics in patients with chronic schizophrenia

Design

A randomized, double-blind, placebo-controlled clinical trial, design of 30 patients with chronic schizophrenia (1: 1 in each group) at 4 months

Settings and conduct

Care centers in Mazandran province

Participants/Inclusion and exclusion criteria

18-65 years old men with the diagnosis of schizophrenia based on DSM-5 criteria for at least two years and despite the anti-psychotic drug treatment, they are still symptomatic. They are treated with antipsychotics for at least one year and In the last month, the type and dosage of their antipsychotic drugs remain constant. If receiving medications such as mood stabilizer or anti depressants, their type and dosage will remain constant from one month before the start of the study and during the study.

Intervention groups

In the intervention group, in addition to prescription antisocycotic treatment, they will receive ondansteron with a dose of 4 mg per day for the first week and 8 mg per day (in two divided doses) for the second week and 12 mg per day (in three divided doses) for the third week to the end of the study (if tolerated). Patients) receive.

Main outcome variables

To assess the severity of patients' psychotic symptoms from PANSS , CGI-S and CGI-I scales, to assess patients' cognitive status from BACS scale , to assess patients' depressive symptoms from CDSS scale and BARS , AIMS and SAS are used to evaluate motor effects at baseline and at the end of the first, second, third, and fourth months. The CGI-I is evaluated at the end of the first, second, third, and fourth months.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120314009297N7**
Registration date: **2020-05-20, 1399/02/31**
Registration timing: **prospective**

Last update: **2020-05-20, 1399/02/31**
Update count: **0**

Registration date

2020-05-20, 1399/02/31

Registrant information

Name

narjes hendouei

Name of organization / entity

mazandaran university of medical science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the efficacy and safety of ondansetron as an adjuvant to antipsychotics in patients with chronic schizophrenia: A randomized, double-blind, placebo-controlled trial

Public title

The effect of ondansetron in patients with residual schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-65 years old male patients Patients with a diagnosis of schizophrenia based on DSM-5 criteria for at least two years who should still be symptomatic despite treatment with antipsychotic medications. Patients should be treated with antipsychotic medications for at least one year, and the type and dose of their antipsychotic medications should remain constant for the last three months. If they are taking medications such as mood stabilizers or antidepressants with their antipsychotic treatment regimen, their type and dose will remain the same for three months before the start of the study and during the study. If they are taking anticholinergic drugs (which include bipyridine or trihexylphenidyl) in combination with their antipsychotic treatment regimen for treatment or prevention the Movement side effects of antipsychotics, the type and dose of them remain stable for three months before the start of and during the study.

Exclusion criteria:

Going to the acute phase of the disease means a 20% increase in the overall score of PANSS (Scizospheria positive and negative evaluation criteria) Patients with acute suicidal behavior or a history of suicide last year, associated psychiatric disorders such as schizo-effective or other psychotic disorders, mental retardation or other cognitive impairment, bipolar disorder and depression, anxiety disorders such as current panic disorder or obsessive-compulsive disorder, Post-traumatic stress disorder, eating disorder History of substance abuse dependence (substance dependence criteria DSM-5) or abuse of substances in the three months prior to the start of the study or positive urine screening test for the substance at the beginning of the study. Patients under ECT in the last six months People with thoughts or actions to harm themselves or others during the study or in the 6 months before the study Patients with neurological disorders such as dementia, delirium, uncontrolled seizures, head trauma, seizure disorder (other than fever-related) and neurodegenerative diseases (such as Alzheimer's, Parkinson's, Stroke, and multiple sclerosis) People with conduction disorders of the heart and other medical / uncontrolled underlying diseases Patients with a history of NMS Patients treated with drugs that affect the patient's cognitive status are based on the criteria of Drugs on the Anticholinergic Burden (ACB) scale (17), such as drugs with anticholinergic properties (except biperidin and trihexifenidyl), hypnotic antihistamines. , Antidepressants Patients with sensitivity to androsterone or other components of the drug or placebo Patients with endangered drug use in the last 6 months

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

ondansetron and placebo tablets are completely similar in terms of color, size, smell and taste produced by a completely similar manufacturing and packagings. Patients were randomly tested in groups. Until the end of the study, no patient or study persons are aware of which drug the patient receives. And anybody other than those who are defective in the study is aware

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moallem street, Moallem square, Vice chancellor for research

City

sari

Province

Mazandaran

Postal code

33971-48157

Approval date

2020-05-04, 1399/02/15

Ethics committee reference number

IR.MAZUMS.REC.1399.164

Health conditions studied

1

Description of health condition studied
Schizophrenia with residual symptoms
ICD-10 code
F20.5
ICD-10 code description
Residual schizophrenia

Primary outcomes

1

Description
Score of general, positive and negative symptoms with Positive and Negative Symptom Scale (PANSS)
Timepoint
At baseline and the end of each month
Method of measurement
Positive and Negative Symptom Scale (PANSS)

2

Description
Score of change in severity of illness based on Clinical Global Impression – Improvement (CGI-I)
Timepoint
At the end of each month
Method of measurement
Clinical Global Impression -Improvement (CGI-I) score

3

Description
Score of severity of illness based on Clinical Global Impression of Severity (CGI-S)
Timepoint
At baseline and at the end of each months
Method of measurement
Clinical Global Impression off Severity (CGI-S)

4

Description
Score of depression symptoms based on Calgary Depression Scale for Schizophrenia
Timepoint
At baseline and at the end of each months
Method of measurement
Brief Assessment of Cognition in schizophrenia

5

Description
Score of SAS for extra pyramidal side effects
Timepoint
At baseline and at the end of each months
Method of measurement
Simpson-Angus Scale (SAS)

6

Description
Score of Barnes Akathisia Rating Scale (BARS)
Timepoint
At baseline and at the end of each months
Method of measurement
Barnes Akathisia Rating Scale (BARS)

7

Description
Score of Abnormal Involuntary Movement Scale (AIMS)
Timepoint
At baseline and at the end of each months
Method of measurement
Abnormal Involuntary Movement Scale (AIMS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Previous prescription antipsychotic treatment + ondosterone drug at a dose of 4 mg per day for the first week and 8 mg per day (in two divided doses) for the second week and 12 mg per day (They are given in three divided doses) for the third week to the end of the study (if patients tolerate it)
Category
Treatment - Drugs

2

Description
Control group: Previous prescription antipsychotic treatment + placebo which is similar to the ondansteron pill in terms of shape, smell, taste, size and color, on a daily basis.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatric care centers in Mazandaran province
Full name of responsible person
Narjes Hendouei
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
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Moallem street, Moallem square-Vice chancellor for research
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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
Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Narjes Hendouei
Position
Assistant Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available