

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the Effect of Ondansetron as Additional Drug on Reducing Negative Symptoms in Hospitalized and Outpatient with Schizophrenia Disorders

Protocol summary

Study aim

Determination of the effects of adding ondansetron to the treatment of negative symptoms of schizophrenia

Design

Clinical trial with control group, with parallel, double-blind, randomized and outcome assessment

Settings and conduct

All admission and outpatient patient referred to the emergency department and psychiatric clinics of 5 azar hospital in Gorgan, which are approved for schizophrenia. Then, all coded patient (blind) and randomly assigned to two groups of control and intervention are divided

Participants/Inclusion and exclusion criteria

All admission and outpatient patient referred to the emergency department and psychiatric clinics of 5 azar hospital in Gorgan, which are approved for schizophrenia

Intervention groups

Patients are randomly assigned to either the ondansetron or placebo groups. Both groups receive risperidone as an antipsychotics. The control group also receives placebo and the case group.

Main outcome variables

Negative symptoms of schizophrenia
Positive symptoms of schizophrenia
Side effects of medication

General information

Reason for update

Acronym

بررسی تأثیر اندانسترون بعنوان داروی کمکی در اختلال اسکیزوفرنیا

IRCT registration information

IRCT registration number: **IRCT20190321043096N1**

Registration date: **2019-04-23, 1398/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-23, 1398/02/03**

Update count: **0**

Registration date

2019-04-23, 1398/02/03

Registrant information

Name

Hedye Mohmoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3605 7872

Email address

mitrajudy@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-04-30, 1398/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Ondansetron as Additional Drug on Reducing Negative Symptoms in Hospitalized and Outpatient with Schizophrenia Disorders

Public title

Evaluation of the Effect of Ondansetron as Additional Drug on Reducing Negative Symptoms in Hospitalized and Outpatient with Schizophrenia Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 age of 18-65 No physical illness No alcohol or drug abuse
 The absence of pregnancy and lactation in women
 PANSS score of more than 15 Acceptance of written consent

Exclusion criteria:
 Drug abuse or alcohol abuse Breastfeeding and pregnancy women The need for other psychotropic drugs during the study

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

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
 Target sample size: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Use random number tables At the beginning of the study, each patient was assigned a code that was recorded on the patient's questionnaire. Then, using the random numbers table and the registered codes, the patients in the intervention group were selected and the remaining patients were assigned to the control group.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 1- subject coding 2- use of placebo is similar to the original medicine

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Golestan Golestan University of Medical Sciences

Street address
 Moslem 19

City
 Mashhad

Province
 Razavi Khorasan

Postal code

۴۴۸۱۶۵۶۷۶۱

Approval date

2018-09-22, 1397/06/31

Ethics committee reference number

IR.GOUMS.REC.1397.105

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20.9

ICD-10 code description

Schizophrenia, unspecified

Primary outcomes

1

Description

Earn score 7-49 in the test of N-PANSS

Timepoint

Before starting the study and 6, 8 and 12 weeks after starting the study

Method of measurement

Based on DSM-5

Secondary outcomes

1

Description

Negative symptoms of schizophrenia

Timepoint

Weeks of 0, 6, 8 and 12

Method of measurement

Evaluation Scale of PANSS

Intervention groups

1

Description

Intervention group: This group receive risperidone as an antipsychotics. Besides that intervention group will receive andonestrone. The dose of ondansetron is 4 mg in the first week and will reach 8 mg in the coming weeks. All subjects at the onset of the study, at weeks 0, 6, 8 and 12, will be evaluated for negative symptoms of schizophrenia by the PANSS scoring scale.

Category

Treatment - Drugs

2

Description

Control group: this group receive risperidone as an antipsychotics. The control group will receive the

placebo. The dose of placebo is 4 mg in the first week and will reach 8 mg in the coming weeks. All subjects at the onset of the study, at weeks 0, 6, 8 and 12, will be evaluated for negative symptoms of schizophrenia by the PANSS scoring scale.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar Hospital in Gorgan

Full name of responsible person

Hedge Mahmoudi

Street address

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City

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Razavi Khorasan

Postal code

4481656761

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+98 51 3605 7872

Email

mitrajudy@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Masome Mirkarimi

Street address

Km 2 Gorgan-Sari Road

City

Gorgan

Province

Golestan

Postal code

۵۶۷۵۸

Phone

+98 17 3245 2658

Email

C_t@goums.ac.ir

Web page address

<http://goums.ac.ir/page/2704>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan University of Medical Sciences

Proportion provided by this source

70

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

Gorgan University of Medical Sciences

Full name of responsible person

Hedye Mahmodi

Position

Resident Psychiatrist

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Moslem 19

City

Mashhad

Province

Razavi Khorasan

Postal code

۴۴۸۱۶۵۶۷۶۱

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The main consequence of the study is the ability to share

When the data will become available and for how long

Two month

To whom data/document is available

Academic Institutions and Psychiatric Clinics

Under which criteria data/document could be used

Improvement in the treatment of schizophrenia

From where data/document is obtainable

Gorgan University of Medical Sciences

What processes are involved for a request to access data/document

Corresponding with the supervisor

Comments