

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Study of the Effect of ondansetron on Negative Symptoms in Schizophrenia

#### Protocol summary

##### Study aim

The aim of study is to evaluate the efficacy of ondansetron in treating schizophrenia

##### Design

In this research, 50 eligible patients with schizophrenia diagnosis according to DSM-IV criteria are enrolled and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

##### Settings and conduct

50 eligible patients with schizophrenia diagnosis referred to Gholabchi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: is based on DSM-IV diagnosis of schizophrenia; ages of subjects were between 25 to 65 years and Exclusion Criteria: patients treated with clozapine; any serious medical or neurological problem; pregnancy and breast feeding.

##### Intervention groups

The intervention group will receive ondansetron 8 mg daily for 12 months. The control group will receive placebo for 12 months.

##### Main outcome variables

Severity of schizophrenia use is evaluated with Positive and Negative Syndrome Scale (PANSS) in the beginning of the study and 4, 8, 12 months after beginning of treatment.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180505039530N1**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

##### Registration date

2018-05-29, 1397/03/08

##### Registrant information

###### Name

Alireza Moteshaker arani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3323 5427

###### Email address

moteshakerarani-a@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-18, 1396/11/29

##### Expected recruitment end date

2019-02-18, 1397/11/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of the Effect of ondansetron on Negative Symptoms in Schizophrenia

##### Public title

Efficacy of ondansetron in the treatment of schizophrenia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Ages of subjects were between 25 to 65 years Is based

on DSM-IV diagnosis of schizophrenia The patient or patient's guardian consent to participate. PANSS score at the beginning of the project is more than 55.

**Exclusion criteria:**

Patients treated with clozapine Pregnancy and breast feeding Any serious medical or neurological problem Hypersensitivity to ondansetron Substance abuse and alcohol Patients who choose to be excluded.

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment will be done by the use of computer-generated random numbers

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Double-blind (both patients and researchers) in your study are blinded

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715973446

**Approval date**

2018-02-12, 1396/11/23

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1396.110

**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**

The beginning of the study and 4, 8, 12 months after beginning of treatment

**Method of measurement**

Positive and Negative Syndrome Scale (PANSS)

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: 8 mg/day of Tablets ondansetron as intervention group for 12 months.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: The control group will receive placebo for 12 months.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Gholabchi Clinic

**Full name of responsible person**

Zahra Sepehrmanesh

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Shahid Rajaei Avenue, Kashan

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Gholamali Hamidi

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Alireza Moteshakerarani

**Position**

Assistant Psychiatrist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

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**Position**

Neuropsychiatrist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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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)**

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

### **Study Protocol**

No - There is not 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