Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of ondanstrone -as an adjuant- in reduction of negative symptoms in schizophrenic inpatients

Protocol summary

Summary

This study is a randomized double-blind clinical trial which is performed on patients with schizophrenia diagnosis admitted in Goolestan hospital psychiatric ward. 48 male and female patients, who are diagnosed as schizophrenics during interviews done by at least two psychiatrists according to DSM-IV TR and have inclusion criteria, will be divided randomly to intervention and control groups (ondanstrone plus atypical antipsychotic and placebo plus atypical antipsychotic). Researcher and person who evaluates will be unaware of this choice. In both groups, The usual starting dose atypical antipsychotic both groups and if needed(1000-2000 mg Chlorpromazine equivalent daily) will increase. In intervention group,4 mg of ondansetron per day in the first week and 8 mg were given in subsequent weeks and in control group placebo prepared like ondanstrone will be added to atypical antipsychotic. These two groups will receive placebo or drug for 6 weeks, Biperiden up to 6 mg per day will be permitted if motor complications occur or if it is necessary. Patients can receive up to 2 mg Clonazepam per day. All patients will be checked at the start and weeks 0, 3 and 6 with PANSS criteria to evaluate negative symptoms of schizophrenia and two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031211071N2**
Registration date: **2014-04-23, 1393/02/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-23, 1393/02/03

Registrant information

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Recruitment status

Recruitment complete

Funding source

Jundishapur University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of ondanstrone -as an adjuant- in reduction of negative symptoms in schizophrenic inpatients

Public title

Evaluation of ondanstrone effect in reduction of negative symptoms in inpatients with schizophrenia disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a diagnosis of schizophrenia according to DSM-IV-TR; an overall score of 50 or higher on the PANSS scale; 15 or higher negative score in PANSS scale; duration of at least 1 year from onset of the illness.

Exclusion criteria: history of sensitivity to ondanstrone; serious medical illness; substance abuse or dependency in recent months; pregnancy; lactation; other simultaneous psychiatric disorders requiring medication; desire to homicide or suicide; having dementia and severe cognitive impairments not bound to schizophrenia; organic brain disorders such as seizure; severe mental retardation and Parkinsonism; consumption of oral antipsychotics during last month or long-acting Injectable forms within three months; Concomitant use of other drugs such as antidepressants; lithium which may interfere in treatment; drug-resistant schizophrenia disorder; lack of response to appropriate dosage and duration of Risperidone.

Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **48**
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
Jundishapur University of Medical Sciences
Street address
2nd floor, School of Medicine Ahvaz Jundishapur University of Medical Sciences, Golestan BLV, Ahvaz
City
Ahvaz
Postal code
Approval date
2012-07-21, 1391/04/31
Ethics committee reference number
ETH- 547

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Negative sign
Timepoint
at the end of weeks 0 ,3 and 6
Method of measurement
PANSS questionnaire

Secondary outcomes

1

Description
Positive sign
Timepoint
at the end of weeks 0 ,3 and 6
Method of measurement
PANSS questionnaire

Intervention groups

1

Description
Intervention group:The usual daily dose atypical anti-psychotic plus 8 mg of ondansetron daily.
Category
Treatment - Drugs

2

Description
The usual daily dose atypical anti-psychotic plus Palacebo daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatry group, Golestan Hospital
Full name of responsible person
DR. Mousa Samadi
Street address
Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences
City

AHVAZ

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
DR. Mostafa Feghhi
Street address
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AHVAZE
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapur 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

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Name of organization / entity
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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