Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Vortioxetine as adjunctive treatment of negative symptoms in patients with schizophrenia: a double blind and placebo controlled trial

Protocol summary

Summary
The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of Vortioxetine would improve psychopathology in subjects with schizophrenia treated with Risperidone. 50 patients with chronic schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=25) or20 mg/day of Vortioxetine (N=25) for 8 weeks. Efficacy will be defined as the change from baseline to endpoint in score on the Positive and Negative Syndrome Scale (PANSS). Side effects will be also evaluated using checklist and Extra-pyramidal Symptoms Rating Scale.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201710241556N100**
Registration date: **2017-10-24, 1396/08/02**
Registration timing: **prospective**

Last update:
Update count: **0**
Registration date
2017-10-24, 1396/08/02

Registrant information
Name
Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2017-11-09, 1396/08/18
Expected recruitment end date
2019-11-08, 1398/08/17
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Vortioxetine as adjunctive treatment of negative symptoms in patients with schizophrenia: a double blind and placebo controlled trial

Public title
Vortioxetine as adjunctive treatment of schizophrenia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:1-Diagnosis of Schizophrenia based on DSM-5 criteria; 2- Age between 18-60; 3-Chronic Schizophrenia- duration of the disorder more than 2 years; 4-Minimum score of 20 in negative sub score. 5-being stable on risperidone for the last 2 months. Exclusion criteria:1-Any serious medical or neurological problem; 2- IQ less than 70; 3- Substance dependence during the last 6 months(except for nicotine and caffeine); 4- Score on HDRS less than 14 5-receiving ECT during the last 3 months ; 6-Acute or chronic systemic diseases; 7- History of neurosurgery; 8- History of head trauma.
Age
From **18 years** old to **60 years** old
Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
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 Tehran University of Medical Sciences
Street address
Keshavarz Blvd.
City
Tehran
Postal code
Approval date
2017-09-23, 1396/07/01
Ethics committee reference number
IR.TUMS.VCR.REC.1396.3556

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
Baseline and weeks 2-4-8 after beginig of treatment
Method of measurement
Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description
Tablet Risperidone (6 mg/day) combined with 20mg/day Vortioxetine as intervention group for 8 weeks
Category
Treatment - Drugs

2

Description
Tablet Risperidone (6 mg/day) combined with placebo as control group for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Dr. Shahin Akhondzadeh
Street address
Roozbeh Hospital, South Kargar Sreet
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Masoud Yunesian
Street address
Keshavarz Blvd.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
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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