Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Tropisetron on negative symptoms in patients with chronic 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 Tropisetron would improve psychopathology in subjects with stable schizophrenia treated with Risperidone. 50 patients with chronic DSM-IV-diagnosed schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=25) or 10 mg/day of Tropisetron (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: **IRCT201106101556N24**
Registration date: **2011-06-12, 1390/03/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date
2011-06-12, 1390/03/22

Registrant information
Name
Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2011-07-06, 1390/04/15
Expected recruitment end date
2012-07-05, 1391/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Tropisetron on negative symptoms in patients with chronic schizophrenia: a double blind and placebo controlled trial

Public title
Tropicetron in the treatment of schizophrenia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Age between 18-50,2-Diagnosis of Schizophrenia based on DSM IV 3-chronic Schizophrenia, 4- minimum Score of 20 on negative subscale of PANSS,5-stable on antipsychotic Exclusion Criteria:1-Substance dependence,2- IQ <70,3-any other mental disorder on axis I, 4-Any serious medical or neurological problem ,5- receiving oral antipsychotic medications during the last week or receiving any depot antipsychotic medication during the last month,6- receiving ECT during the last 14 days
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2
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
Tehran University of Medical Sciences
Street address
Keshavarz Blvd
City
Tehran
Postal code
Approval date
2011-05-05, 1390/02/15
Ethics committee reference number
11426

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
Severity of schizophrenia
Timepoint
Baseline and weeks 2-4-6-8 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 10mg/day of Tablets tropisetron as intervention group for 8 weeks
Category
Treatment - Drugs

2

Description
Tablets Risperidone (6 mg/day) combined with Tablets placebo as control group for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Prof. Shahin Akhondzadeh
Street address
south kargar street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Prof. Shahin Akhondzadeh
Position
Prof. of Clinical Psychopharmacology
Other areas of specialty/work
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Person responsible for updating data

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Email
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Web page address

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