

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

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

Protocol summary

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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

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

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)

Phone

+98 21 5541 2222

Email address

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**Street address**

Roozbeh Hospital-South Karegar street

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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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*