Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Sildenafil add on therapy to risperidone in the treatment of the negative symptoms of schizophrenia: a double-blind randomized placebo-controlled study.

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of sildenafil would improve psychopathology in subjects with schizophrenia treated with Risperidone. 40 patients with chronic DSM-IV-diagnosed schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=20) or 75 mg/day of sildenafil (N=20) 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: **IRCT1138901151556N11**
Registration date: **2010-04-29, 1389/02/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-04-29, 1389/02/09

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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical sciences

Expected recruitment start date

2010-03-01, 1388/12/10

Expected recruitment end date

2010-05-01, 1389/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sildenafil add on therapy to risperidone in the treatment of the negative symptoms of schizophrenia: a double-blind randomized placebo-controlled study.

Public title

Sildenafil the treatment of the negative symptoms of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age between 18-55, Diagnosis of Schizophrenia based on DSM IV 3 chronic Schizophrenia, Minimum Score of 60 on Positive and Negative Scale
Exclusion Criteria: Substance dependence, Pregnancy and breast feeding, Any serious medical problem

Age

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

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
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
2009-05-12, 1388/02/22
Ethics committee reference number
6551

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 2-4-6-8 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 75 mg/day of Tablets sildenafil 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
Treatment - Drugs

Recruitment centers

1

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

2

Recruitment center
Name of recruitment center
Department of Psychiatry
Full name of responsible person
Dr. Bahman Salehi
Street address
Arak University of Medical Sciences
City
Arak

3

Recruitment center
Name of recruitment center
Department of Psychiatry
Full name of responsible person
Dr. Farzin Rezaei
Street address
Department of Psychiatry
City
Sanandaj

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
6551
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
Ph.D.
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Person responsible for updating data

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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