

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Email address

s.akhond@sina.tums.ac.ir

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.

Other areas of specialty/work

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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