

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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**

**Street address**

Roozbeh Hospital

**City**

Tehran

**Postal code**

**Phone**

+98 21 5541 2222

**Fax**

**Email**

s.akhond@sina.tums.ac.ir

**Web page address**

### Person responsible for updating data

#### 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**

**Street address**

Roozbeh Hospital

**City**

Tehran

**Postal code**

**Phone**

+98 215541222

**Fax**

**Email**

s.akhond@sina.tums.ac.ir

**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*