

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Duloxetine as adjunctive treatment of negative symptoms in patients with 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 Duloxetine would improve psychopathology in subjects with schizophrenia treated with Risperidone. 50 patients with chronic schizophrenia will receive Risperidone (4-6 mg/day) combined with either placebo (N=25) or 60 mg/day of Duloxetine (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: **IRCT201506201556N77**

Registration date: **2015-06-21, 1394/03/31**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-06-21, 1394/03/31

##### 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

2015-06-22, 1394/04/01

##### Expected recruitment end date

2015-09-23, 1394/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Duloxetine as adjunctive treatment of negative symptoms in patients with schizophrenia: a double blind and placebo controlled trial

##### Public title

Duloxetine in patients with schizophrenia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1-Diagnosis of Schizophrenia based on DSM-5 criteria; 2- Age between 18-60; 3-Chronic Schizophrenia- duration of the disorder more than 2 years; 4-Minimum score of 20 in negative sub score. 5- being stable on risperidone for the last 2 months  
Exclusion criteria: 1-Any serious medical or neurological problem; 2- IQ less than 70; 3- Substance dependence during the last 6 months(except for nicotine and caffeine); 4- Score on HDRS less than 14 5-receiving ECT during the last 3 months ; 6-Acute or chronic systemic diseases; 7- History of neurosurgery; 8- History of head trauma

##### Age

From **18 years** old to **60 years** old

##### Gender

Both

## Phase

2-3

## 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

Ethics Committee of Tehran University of Medical Sciences

##### Street address

Keshvarz Blvd

##### City

Tehran

##### Postal code

#### Approval date

2015-04-21, 1394/02/01

#### Ethics committee reference number

23244

## 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 2-4-8 after beginig of treatment

#### Method of measurement

Positive and Negative Syndrome Scale (PANSS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Tablet Risperidone (4-6 mg/day) combined with60 mg/day Duloxetine as intervention group for 8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Tablet Risperidone (4-6 mg/day) combined with 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 Kregar street, Roozbeh Hospital

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr Masoud Ynesian

##### Street address

Tehran University of Medical Sciences, Keshvarz 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***Postal code****Phone**

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**Fax****Email**

s.akhond@sina.tums.ac.ir

**Web page address****Person responsible for general 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**

South Kargar street; Roozbeh Hospital

**City**

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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*