

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

raloxifene as an add-on therapy in men with chronic schizophrenia: a randomized 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 Raloxifene would improve psychopathology in subjects with schizophrenia treated with Risperidone. 46 male patients with chronic schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=23) or 6 g/day of Raloxifene (N=23) 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: **IRCT201211211556N47**

Registration date: **2012-11-24, 1391/09/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-24, 1391/09/04

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

2012-11-21, 1391/09/01

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

raloxifene as an add-on therapy in men with chronic schizophrenia: a randomized double blind and placebo controlled trial

Public title

Raloxifene in men with chronic schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria:1-Diagnosis of Schizophrenia based on DSM- IV criteria;2- Minimum Score of 60 on Positive and Negative Scale 3- Age between 18-55;4-male sex 5- chronic Schizophrenia- duration of the disorder more than 2 years; ; 6-Minimum score of 20 in negative suscore Exclusion Criteria:1-any other mental disorder on axis I; 2-Any serious medical or neurological problem; 3- IQ less than 70;4- Substance dependence during the last 6 months(except for nicotine and caffeine) 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, 7- Endocrine abnormality; 8-hepatic and renal disease 9- history of thrombosis and embolism 10 history of abnormal bleeding 11- CVA

Age

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

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **46**

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**

2012-11-18, 1391/08/28

Ethics committee reference number

19268

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**

Tablets Risperidone (6 mg/day) combined with 120 mg/day Raloxifene as intervention group for 8 weeks

Category

Treatment - Drugs

2**Description**

Tablet Risperidone (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

Dr. Shahin Akhondzadeh

Street address

South Kargar Sreet, Roozbeh Hospital

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Prof. Akbar Fotouhi

Street address

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

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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