Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of raloxifene in postmenopausal women 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 postmenopausal women with schizophrenia treated with Risperidone. 46 postmenopausal women with chronic DSM-IV-diagnosed schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=23) or 120 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: **IRCT201205131556N42**
Registration date: **2012-05-13, 1391/02/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-05-13, 1391/02/24

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

2012-06-21, 1391/04/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of raloxifene in postmenopausal women with chronic schizophrenia: a randomized double blind and placebo controlled trial

Public title

Raloxifene in the treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Postmenopausal women, Diagnosis of Schizophrenia based on DSM IV , chronic Schizophrenia(duration of the disorder>2 years), Minimum Score of 20 on Negative subscale Exclusion Criteria: Substance dependence(except for nicotine and cafeine), IQ <70, any other mental disorder on axis I, Any serious medical or neurological problem , receiving oral antipsychotic medications during the last week or receiving any depot antipsychotic medication during the last month, receiving ECT during the last 14 days,hepatic and renal disease , Endocrine abnormality, history of thrombosis and emboli, history of abnormal uterine bleeding, uterine or breast cancer, history of CVA, Hormone replacement therapy

Age
No age limit
Gender
Female

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
2012-05-08, 1391/02/19
Ethics committee reference number
17215

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
Roozbeh Hospital; South Karegar Street
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

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

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