Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Riluzole on negative symptoms in patients with chronic 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 Riluzole would improve psychopathology in subjects with schizophrenia treated with Risperidone. 30 patients with chronic DSM-IV-diagnosed schizophrenia will receive Risperidone (2-6 mg/day) combined with either placebo (N=15) or 100 mg/day of Riluzole (N=15) 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: **IRCT201107281556N26**
Registration date: **2011-07-30, 1390/05/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-07-30, 1390/05/08

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

2011-09-23, 1390/07/01

Expected recruitment end date

2012-06-23, 1391/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Riluzole on negative symptoms in patients with chronic schizophrenia: a double blind and placebo controlled trial

Public title

Riluzole in the treatment of the negative symptoms of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria:1- Age between 18-50, 2- Diagnosis of Schizophrenia based on DSM IV 3- chronic Schizophrenia(the duration of the disorder> 2 years), Minimum Score of 60 on Positive and Negative Scale- Exclusion Criteria:1- Substance dependence,2- IQ <70,3-any other mental disorder on axis I, 4-Any serious medical or neurological problem ,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- hepatic disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
Added at :
Secondary trial Id
Added at :
Registration date
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
2011-07-17, 1390/04/26
Ethics committee reference number
14037

Health conditions studied

1

Description of health condition studied
schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Change in the severity of negative symptoms
Timepoint
Baseline and weeks 2, 4, 6 and 8 after begining of treatment
Method of measurement
Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

1

Description
Change in other PANSS subscale scores
Timepoint
Weeks: 2, 4, 6 and 8
Method of measurement
Positive and Negative Syndrome Scale (PANSS)

Intervention groups

1

Description
Tablet Risperidone (2-6 mg/day) combined with 100 mg/day of Tablets Riluzole as intervention group for 8 weeks
Category
Treatment - Drugs

2

Description
Tablets Risperidone (2-6 mg/day) combined with Tablets 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 kargar street
City
Tehran

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

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

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Prof. Shahin Akhondzadeh

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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