Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Efficacy of Adjunctive L-lysine in Patients with Chronic Schizophrenia: A Randomized, Double-Blinded, Placebo-Controlled Trial

Protocol summary

Summary

The objective of this randomized, double-blinded, placebo-controlled study is to test the hypothesis that the addition of L-lysine would improve psychopathology in subjects with schizophrenia treated with Risperidone. 72 patients with chronic DSM-IV-diagnosed schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=35) or 6 g/day of L-Lysine (N=35) 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: **IRCT201202201556N33**
Registration date: **2012-02-22, 1390/12/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-02-22, 1390/12/03

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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-03-01, 1390/12/11

Expected recruitment end date

2014-03-01, 1392/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Adjunctive L-lysine in Patients with Chronic Schizophrenia: A Randomized, Double-Blinded, Placebo-Controlled Trial

Public title

L-Lysine in the treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age between 18-50, Diagnosis of Schizophrenia based on DSM IV 3 chronic Schizophrenia(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: **70**
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
2012-02-20, 1390/12/01
Ethics committee reference number
16005

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 6 g/day L-Lysine 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 Sreeet
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
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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