Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

N-acetyl cysteine add on therapy to risperidone in the treatment of the negative symptoms of schizophrenia: a double-blind randomized placebo-controlled study.

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of N-acetyl cysteine 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 2000mg/day of N-acetyl cysteine (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: **IRCT201106031556N21**
Registration date: **2011-06-08, 1390/03/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-06-08, 1390/03/18

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 SciencesKurdistan University of Medical Sciences

Expected recruitment start date

2011-06-23, 1390/04/02

Expected recruitment end date

2012-06-22, 1391/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

N-acetyl cysteine add on therapy to risperidone in the treatment of the negative symptoms of schizophrenia: a double-blind randomized placebo-controlled study.

Public title

The effect of N- Acetyl cysteine on symptoms in patients with chronic schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1-Age between 18-50, 2-Diagnosis of Schizophrenia based on DSM IV 3-chronic Schizophrenia, 4-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-

sensitivity to N-acetyl cysteine

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

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
2011-05-05, 1390/02/15

Ethics committee reference number
11918

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
ablet Risperidone (2-6 mg/day) combined with 2000 mg/day of Tablets N-acetyl cysteinel as intervention group for 8 weeks

Category
Treatment - Drugs

2

Description
ablets 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

2

Recruitment center

Name of recruitment center
Qhods Hospital

Full name of responsible person
Farzin Rezaei

Street address
Pasdaran Blvd- Qhods hospital - Sanandaj

City
Sanandaj

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

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

2

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Dr Ataollah Heydari

Street address

Pasdaran Blvd-Kurdistan university of Medical Sciences-Deputy of research- Sanandaj

City

Sanandaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kurdistan University of Medical Sciences

Proportion provided by this source

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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Name of organization / entity

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Full name of responsible person

Prof. Shahin Akhondzadeh

Position

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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