

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Acetaminophen as an adjuvant in the treatment of chronic schizophrenia: a double blind and randomised trial

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the effect of Acetaminophen as an adjuvant in patients with schizophrenia. 50 patients with chronic schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=25) or 325 mg/day of Acetaminophen (N=25) 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: **IRCT201410251556N67**
Registration date: **2014-10-28, 1393/08/06**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-28, 1393/08/06

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

2014-11-03, 1393/08/12

Expected recruitment end date

2015-01-31, 1393/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Acetaminophen as an adjuvant in the treatment of chronic schizophrenia: a double blind and randomised trial

Public title

Acetaminophen in the treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria:1-Diagnosis of Schizophrenia based on DSM-5 criteria;2- Minimum Score of 60 on Positive and Negative Scale 3- Age between 18-55; 4- chronic Schizophrenia- duration of the disorder more than 2 years; ; 6-Minimum score of 20 in negative suscale
Exclusion Criteria:1-any other major mental disorder based on DSM-5; 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-hepatic and renal disease; 7- history of abnormal bleeding

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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**

2014-09-23, 1393/07/01

Ethics committee reference number

26263

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 2-4-8 after beginig of treatment

Method of measurement

by Positive and Negative Symptoms Scale(PANSS)

Secondary outcomes**1****Description**

extrapyramidal side effects

Timepoint

Baseline and weeks 2-4-6-8 after beginig of treatment

Method of measurement

by Extrapyramidal Symptoms Rating Scale

Intervention groups**1****Description**

Tablets Risperidone (6 mg/day) combined with 325 mg/day Acetaminophen 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

Prof. 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

Dr Masoud Yunesian

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**Street address**

Roozbeh Hospital, South Karegar street

City

Tehran

Postal code**Phone**

+98 21 5541 2222

Fax**Email**

s.akhond@neda.net; sakhond@yahoo.com;

s.akhond@sina.tums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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s.akhond@sina.tums.ac.ir

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*