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

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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
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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