Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Pentoxifylline as an adjuvant therapy in the treatment of negative symptoms of Schizophrenia: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim
Investigating the effect of Pentoxifylline for the treatment of negative symptoms of Schizophrenia

Design
Randomized double blind and placebo-controlled clinical trial

Settings and conduct
The study will be performed on patients with chronic schizophrenia attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of schizophrenia based on DSM-5 - Age between 18-60 - At least 2 years have been passed since the diagnosis - <14 HDRS score - >15 PANSS score for negative symptoms. Exclusion criteria Head trauma - History of shock therapy during the last three months - Neurosurgery - Diagnosis of acute or chronic systemic disease - History of drug allergy to risperidone or pentoxifylline - Alcohol or drug addiction in the last 6 months - Suicidal ideation - Pregnancy or lactation - IQ less than 70 based on the diagnosis of a psychiatrist.

Intervention groups
Intervention group: Patients treated with risperidone 4-6 mg per day + Pentoxifylline 400 mg twice a day for 8 weeks. Control group: Patients treated with risperidone 4-6 mg per day + placebo twice a day for 8 weeks.

Main outcome variables
Severity of schizophrenia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N143**
Registration date: **2022-05-26, 1401/03/05**
Registration timing: **prospective**
Last update: **2022-05-26, 1401/03/05**
Update count: **0**

Registration date
2022-05-26, 1401/03/05

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

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2024-06-21, 1403/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Pentoxifylline as an adjuvant therapy in the treatment of negative symptoms of Schizophrenia: A randomized double blind and placebo controlled clinical trial

Public title
Pentoxifylline for the treatment of negative symptoms of

Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of schizophrenia based on DSM-5 Age between 18-60 At least 2 years have been passed since the diagnosis Have been stable with risperidone treatment for at least 2 months <14 HDRS score >15 PANSS score for negative symptoms

Exclusion criteria:

Head trauma History of shock therapy during the last three months Neurosurgery Diagnosis of acute or chronic systemic disease History of drug allergy to risperidone or pentoxifylline Alcohol or drug addiction in the last 6 months Suicidal ideation Pregnancy or lactation IQ less than 70 based on the diagnosis of a psychiatrist.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups). The best way to create randomization is to use random allocation. Random allocation in clinical trial studies refers to the process of randomly dividing participants into different groups. Randomization gives each participant an equal chance to participate in each group. Successful randomization requires that researchers and study participants be unable to predict the type of intervention received.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine Ethics Committee, Tehran University of Medical Sciences

Street address

School of Medicine, Tehran University of Medical Sciences, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-03-19, 1400/12/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.159

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 4 and 8

Method of measurement

By Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients (25 participants) treated with risperidone 4-6 mg per day + Pentoxifylline 400 mg twice a day for 8 weeks.

Category

Treatment - Drugs

2

Description
Control group: Patients (25 participants) treated with risperidone 4-6 mg per day + placebo twice a day for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh hospital
Full name of responsible person
Dr. Mohammad Reza Mohammadi
Street address
Roozbeh Hospital, South Kargar Street, Tehran
City
Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.
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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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Shahin Akhondzadeh
Position
Professor of clinical psychopharmacology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Position
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The data will be distributed through final report

When the data will become available and for how long
5 years from 2023 to 2028

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Users should cite the resource of data

From where data/document is obtainable
Prof Shahin Akhondzadeh

What processes are involved for a request to access data/document
By E-mail

Comments