Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of pentoxifylline adjunctive therapy on cognitive deficits and symptoms of patients with schizophrenia: A randomized placebo-controlled clinical trial

Protocol summary

Study aim
Improving symptoms and cognitive function level in schizophrenic patients

Design
A randomized, double-blind, placebo-controlled clinical trial in phase 3 clinical trials with parallel groups of 26 patients in each group

Settings and conduct
This study is performed on 52 patients with schizophrenia admitted to Ibn-Sina hospital in Mashhad. The treatment is completely blind and the patient, therapist and evaluator are not aware of the type of drug. Pentoxifylline tablets are added to the treatment regimen of a group of patients with schizophrenia and their effects are evaluated by tests performed at baseline, 4 and 8 weeks after treatment.

Participants/Inclusion and exclusion criteria
Patients 18-55 years in the hospital who were diagnosed with schizophrenia by their psychiatrist and confirmed by a psychiatric assistant with a structured interview based on DSM-5, completed the entry and exit conditions, and the patient or the patient's legal guardian has given consent to enter the study

Intervention groups
Assessment tests are first performed by the evaluator and psychiatric assistant, then patients in both groups are treated with standard schizophrenia's treatment including 2nd generation antipsychotics (including risperidone to 6mg, or olanzapine to 30mg or aripiperazole to 30mg) and benzodiazepine, anticholinergic and betablocker if needed. Patients are also randomly divided into 2 groups of drug and placebo using random numbers table. One group receive 400 mg of pentoxifylline, 3 times daily for 8 weeks, and the other group receive placebo 3 times daily for 8 weeks. Initial evaluation tests are repeated for 4 to 8 next weeks.

Main outcome variables
Positive and negative symptoms of schizophrenia; Cognitive impairments

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190914044769N1**
Registration date: **2020-03-07, 1398/12/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-07, 1398/12/17**
Update count: **0**

Registration date
2020-03-07, 1398/12/17

Registrant information

Name
Farideh Sinichi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3846 6701

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of pentoxifylline adjunctive therapy on cognitive deficits and symptoms of patients with schizophrenia: A randomized placebo-controlled clinical trial

Public title

Effect of Pentoxifylline in treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of schizophrenia based on DSM-5 criteria Patients aged 18-55 years Completion of the consent form by the patient or his / her family Education level at least eighth grade Absence of other concurrent psychiatric disorders Absence of liver and kidney disorders Absence of medical illness leads to psychiatric symptoms No substance use except for smoking Absence of serious cognitive impairment Absence of risk factor for bleeding Patients who are prescribed antipsychotics for risperidone, olanzapine or aripiperazole. Onset of illness under 45 years

Exclusion criteria:

Hypersensitivity reaction or any unbearable side effect caused by the drug Unwillingness to continue taking the drug and continue the project

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs and placebo are packaged and numbered by the pharmacist and provided to the researcher and then the therapeutic units. Study participants were unaware that the drug they were taking was a drug or a placebo, knowing that the drug was added to other drugs to improve their condition. The lead researcher, who drafts the article, entered the patients and prescribed the medication in their prescription don't know which patients are given the drug or placebo. Nurses who take care of patients and give patients drugs have been kept blind in the study because they give the medicine from the same numbered envelopes to the patients, and the doctors who check the medication's side effects; They have been kept blind from the study. Data collectors and those assessing outcomes also lack information on drug and placebo groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran national committee for ethics in biomedical research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

9999999999

Approval date

2019-06-09, 1398/03/19

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.821

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

cognitive scores according to Stroop, Ray, Digit span, and Wisconcin card sorting test

Timepoint

Evaluation of cognitive impairments and positive and negative symptoms of schizophrenia at baseline (before intervention) and 4 and 8 weeks after starting

pentoxifylline

Method of measurement

Positive and Negative Syndrome Scale, cognitive tests include Stroop, Ray, Digit span, and Wisconcin card sorting test

Secondary outcomes

1

Description

score of Positive and Negative Syndrome Scale

Timepoint

Baseline (before intervention) and 4 and 8 weeks after starting pentoxifylline

Method of measurement

Positive and Negative Syndrome Scale

Intervention groups

1

Description

To the intervention group is given 400mg extended release pentoxifylline pills from Hakim Pharmaceutical Company every 8 hours for 2 months. Pentoxifylline is a class of aminophyllins.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebn-Sina hospital

Full name of responsible person

Farhad Faridhoseini

Street address

Bou-Ali square., Hor Ameli blvd., Ibn-Sina hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Psychiatry and Behavioral Sciences Research Center

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

70

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

Mashhad University of Medical Sciences

Full name of responsible person

Fsrhad Faridhoseini

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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inquiries

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Specialist

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The full statistical report will be published in detail on the data of the questionnaires in the paper.

When the data will become available and for how long
from 2020

To whom data/document is available
The data report will be published in the article.

Under which criteria data/document could be used
The data report will be published in the article.

From where data/document is obtainable
The data report will be published in the article.

What processes are involved for a request to access data/document
The data report will be published in the article.

Comments