

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of Cyproheptadine on relieving the negative and positive symptoms of patients with schizophrenia or schizoaffective

Protocol summary

Study aim

Determining the effect of Cyproheptadine on reducing the positive and negative symptoms of schizophrenia patients based on Positive and Negative Syndrome Scale (PANSS) criteria.

Design

Two arm parallel group randomized trial with non blinded outcome assessment

Settings and conduct

In this randomized clinical trial, outpatients and inpatients of the psychiatric ward of Taleghani Hospital affiliated to Shahid Beheshti University of Medical Sciences, who were diagnosed with schizophrenia according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and were randomly divided into two groups, will be included in the study. During this study, 30 patients with schizophrenia in two groups of 15 people (one group receiving Cyproheptadine and one control group) will be studied for 6 weeks and outcome will be measured in the first, second, fourth and sixth weeks of the study based on PANSS criteria

Participants/Inclusion and exclusion criteria

Inclusion criteria: ages 18-65 Diagnosis of schizophrenia or schizoaffective disorder (depressive type) based on DSM-V taking risperidone as an antipsychotic; exclusion criteria: Antipsychotic treatment other than risperidone, Drug abuse, Thyroid disorder, pregnancy and lactation.

Intervention groups

Intervention group: receiving Cyproheptadine by dose of 8 mg per day in form of two 4mg tablet twice a day in addition to receiving risperidone 4-6 mg daily as an antipsychotic. control group: receiving risperidone 4-6 mg daily as an antipsychotic

Main outcome variables

Positive and Negative symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N22**

Registration date: **2021-07-05, 1400/04/14**

Registration timing: **prospective**

Last update: **2021-07-05, 1400/04/14**

Update count: **0**

Registration date

2021-07-05, 1400/04/14

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Cyproheptadine on relieving the

negative and positive symptoms of patients with schizophrenia or schizoaffective

Public title
Cyproheptadine in Schizophrenia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Ages 18-65 years Diagnosis of schizophrenia or schizoaffective disorder (Depressive type) based on DSM-V Taking Risperidone as an Antipsychotic Fill in the consent
Exclusion criteria:
Antipsychotic treatment other than Risperidone History of non-response to second generation antipsychotic treatment Drug abuse Thyroid Disorder Pregnancy and Lactation

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Individual Randomization with the Card in Two Groups A and B, in this Way a Number of Cards are selected as the first Intervention Group and the same Number in the control Group, then by merging the Cards together one Card is drawn and its Allocation is recorded and the Card is returned to the other Cards after it has been removed. The Cards are then re-merged and another Card is withdrawn. The Process continues until a Random Sequence Sample Size is reached.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

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Postal code

1996835113

Approval date

2020-06-01, 1399/03/12

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.056

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Positive and Negative Syndrome

Timepoint

At the beginning of the study, the first week, the second week, the fourth week, the sixth week

Method of measurement

PANSS Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving Cyproheptadine by dose of 8 mg per day in form of two 4mg tablet twice a day in addition to receiving risperidone 4-6 mg daily as an antipsychotic.

Category

Treatment - Drugs

2

Description

Control group: receiving risperidone 4-6 mg daily as an antipsychotic

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani hospital

Full name of responsible person

Maria Tavakoli-Ardakani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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Shahid Beheshti School of Pharmacy, Hashemi Rafsanjani Highway ,Valiasr St.

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farnaz Kongi

Position

Student of Pharmacy

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available