

# 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)

##### Phone

+98 21 8887 3704

##### Email address

mariatavakoli@sbmu.ac.ir

##### 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

Tehran

##### 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

**Street address**

Taleghani Educational Hospital, Tabnak St. Velenjak Region, Chamran High Way, Tehran, Iran

**City**

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**Province**

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**Postal code**

1985711151

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**Email**

mariatavakoli@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Zarghi

**Street address**

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

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Mpajouhesh@sbmu.ac.ir

**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

**Street address**

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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

Student of Pharmacy

**Latest degree**

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**Other areas of specialty/work**

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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