

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### The effectiveness of cyproheptadine in the treatment of acute akathisia caused by neuroleptics

#### Protocol summary

##### Study aim

Determining the effectiveness of cyproheptadine in the treatment of acute akathisia caused by neuroleptics

##### Design

Clinical trial with a control group, with parallel groups, double-blind, validated, phase 3 on 50 patients, 4 random blocks method is used for validation.

##### Settings and conduct

The study will be conducted on patients hospitalized in Sanandaj Quds Hospital and the psychosomatic department of Kausar Hospital who were taking antipsychotics, so that they are divided into two intervention and control groups, cyproheptadine is prescribed to the intervention group and placebo to the intervention group. Blinding is done in such a way that only the co-designer of the plan knows which patient will receive the drug and which placebo, and the patient and the doctor do not know about the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Get antipsychotic, A minimum score of 2 on the akathisia scale is obvious Exclusion criteria: Get betablocker, cyproheptadine ,miancerin, Vitamin B6, suicided thought severe, Severe akathisia(score higher than 5 in BARS)

##### Intervention groups

Intervention and control group Intervention group: The intervention is cyproheptadine, which is prepared by a pharmacist in the form of capsules. Control group: placebo capsule, which is completely similar to the original drug in terms of shape, color and smell.

##### Main outcome variables

Akathisia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191218045795N7**

Registration date: **2023-02-25, 1401/12/06**

Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**

Update count: **0**

##### Registration date

2023-02-25, 1401/12/06

##### Registrant information

###### Name

Narges Shams alizadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 87 3366 8821

###### Email address

n.shamsalizadeh@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-21, 1402/01/01

##### Expected recruitment end date

2023-08-23, 1402/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of cyproheptadine in the treatment of acute akathisia caused by neuroleptics

##### Public title

The effectiveness of cyproheptadine in the treatment of acute akathisia caused by neuroleptics

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Get antipsychotic A minimum score of 2 on the akathisia scale BARS

### Exclusion criteria:

Receiving beta blocker, mianserin, cyproheptadine, vitamin B6 Suicidal thoughtsevere Severe akathisia (score higher than 5 in BARS)

## Age

From **20 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

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

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

4 - block allocationrandom Patients are placed in two groups A and B by the assistant using the randomized block method. For this randomization, pre-prepared cans and medicines are made by the pharmacist and based on the patients in the order provided by the statistical consultant. The patient and the outcome researcher are unaware of which of the two groups is receiving the medication or placebo. Random allocation method: Individuals are assigned to the intervention and control groups using the method of forming 4 random blocks as follows. AABB, ABAB, BBAA, BABA A: Intervention Group B: Control Group Up to 48 people are randomized using the formation of 4 random blocks and random selection from the sequence of these blocks. For the remaining two people, each of them will be placed in one of the intervention and control groups using the lottery method.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Placebo was made of inert substances designed to have no effect. In this study, except for the pharmacist who prepared the medication and placebo, all the other people including psychiatrists, patients, and researchers were blind to the study groups.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

##### Street address

No.1, Pasdaran Street, Sanandaj, Kurdistan, Iran, Kurdistan University of Medical Sciences

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

6617913141

#### Approval date

2022-11-08, 1401/08/17

#### Ethics committee reference number

IR.MUK.REC.1401.340

## Health conditions studied

### 1

#### Description of health condition studied

Akathisia

#### ICD-10 code

G25.71

#### ICD-10 code description

Drug induced akathisia

## Primary outcomes

### 1

#### Description

BARS akathisia score

#### Timepoint

At the beginning of the study (before the start of the intervention) and 5 days after the start of cyproheptadine

#### Method of measurement

BARS akathisia questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention in this study is Cyproheptadine. First, Cyproheptadine powder (manufactured by Tekaje-Iran ) which is prepared by a pharmacologist, is poured into empty capsules in the amount of 4 mg with empty scales. Cyproheptadine is easily poured from The gastrointestinal tract is absorbed and reaches the maximum blood level within two hours.

Extensively metabolized in the liver, the most important biotransformation pathways of this drug are demethylation and oxidation. The capsules are then given to the patients in the intervention group by a trained nurse for 4 days at 9 pm.

#### Category

Treatment - Drugs

## 2

#### Description

Control group: Placebo is prepared based on the color of the requested powder (including flour, starch and pigment) and in the amount of 15 mg in the same capsules where the drug was poured, and it is completely the same shape, color and smell of Cyproheptadine. It also has no effect on acacia.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Qods hospital

##### Full name of responsible person

Narges Shamsalizadeh

##### Street address

No.1, Pasdaran Street, Sanandaj, Kurdistan, Iran,  
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##### City

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##### Postal code

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##### Phone

+98 87 3366 0025

##### Email

n.shamsalizadeh@muk.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Kwsar hospital

##### Full name of responsible person

Narges Shamsalizadeh

##### Street address

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sanandaj University of Medical Sciences

##### Full name of responsible person

Afshin Malaki

##### Street address

No.1, Pasdaran Street, Sanandaj, Kurdistan, Iran,  
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##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

Nshamsalizadeh@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

##### Full name of responsible person

Narges Shamsalizadeh

##### Position

Associated profesor

##### Latest degree

Specialist

##### Other areas of specialty/work

Psychiatrics

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##### Province

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## Person responsible for scientific inquiries

### Contact

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Sanandaj University of Medical Sciences  
**Full name of responsible person**  
Narges Shamsalizadeh  
**Position**  
Associated professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Psychiatrics  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Sanandaj University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Associated professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**

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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

Yes - There is a plan to make this available

### Title and more details about the data/document

Participant individual data

### When the data will become available and for how long

6 months after publication

### To whom data/document is available

People working in academic institutions

### Under which criteria data/document could be used

Researcher working on academic institution

### From where data/document is obtainable

Nshamsalizadeh@yahoo.com

### What processes are involved for a request to access data/document

The application must be sent by the applicant to the research vice-chancellor of the University of Medical Sciences, if approved by the relevant vice-chancellor, the files will be sent via email.

### Comments