# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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 pharmacologist 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 Suiccidal 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 questionaire

## 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

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**2**

**Recruitment center**

**Name of recruitment center**

Kwsar hospital

**Full name of responsible person**

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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

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

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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**

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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
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**