# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Aug 2026

## The effect of mirtazapine on neuroleptic-induced acute akathisia

### Protocol summary

**Study aim**
The Efficacy of mirtazapine on Acute Neuroleptic-Induced Akathisia
**Design**
Clinical trial with control group, double-blind randomized. In two groups of intervention and control with 48 samples
**Settings and conduct**
The study was performed on patients admitted to Ghods Hospital in Sanandaj who were taking antipsychotics.
**Participants/Inclusion and exclusion criteria**
inclusio :currently on antipsychotic medication; a score of at least 2(mild akathisia) on the global subscale of theBarnes Akathisia Rating Scale (BARS) exclusion:taking betablocker, cyproheptadin ,miancerin,B6 suiccidal thought severe akathisia ,global score of BARS >5
**Intervention groups**
The intervention in this study is mirtazapine. Mirtazapine powder is first prepared by a pharmacologist and then weighed with a scale of 10 mg. Pour 15 mg of mirtazapine powder into each capsule.
**Main outcome variables**
akathisia, BARS (Barns Akathisia Rate Scale)

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20191218045795N5**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-17, 1400/12/26**
Update count: **0**
**Registration date**
2022-03-17, 1400/12/26

**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**
2022-02-07, 1400/11/18
**Expected recruitment end date**
2022-07-09, 1401/04/18
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of mirtazapine on neuroleptic-induced acute akathisia

**Public title**
The effect of mirtazapine on neuroleptic-induced acute akathisia
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
currently onantipsychotic medication; a score of at least 2(mild akathisia) on the global subscale of theBarnes Akathisia Rating Scale (BARS)
**Exclusion criteria:**
aking betablocker, cyproheptadin ,miancerin, Vitamin B6 suiccidal thoughtsevere akathisia ,global score of BARS >5
**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
- Data and Safety Monitoring Board

**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**

IR.MUK.REC.1397.310

**Street address**

Pasdaran

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617978743

**Approval date**

2022-02-06, 1400/11/17

**Ethics committee reference number**

IR.MUK.REC.1400.280

## Health conditions studied

**1**

**Description of health condition studied**

آکاتیزیا

**ICD-10 code**

G25.71

**ICD-10 code description**

Drug induced akathisia

## Primary outcomes

**1**

**Description**

BARS akathisia score

**Timepoint**

before intervention and 5 day after intervention

**Method of measurement**

BARS akathisia questionaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: The intervention in this study is mirtazapine. First, mirtazapine powder (manufactured by Tekaje-Iran under the brand name Rpizapine) which is prepared by a pharmacologist, is poured into empty capsules in the amount of 15 mg with empty scales. Mirtazapine 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 7 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 mirtazapine. It also has no effect on acacia.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Quds Hospital and Kusar Hospital

**Full name of responsible person**
Narges Shamsalizadeh

**Street address**
Entezam Blvd

**City**
sanandaj

**Province**
Kurdistan

**Postal code**
6617113141

**Phone**
+98 87 3366 0025

**Email**
nshamsalizadeh@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Sanandaj University of Medical Sciences

**Full name of responsible person**
Afshin Malaki

**Street address**
Pasdaran Blv.

**City**
sanandaj

**Province**
Kurdistan

**Postal code**
6617978743

**Phone**
+98 87 3366 4957

**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**
Medical doctor

**Other areas of specialty/work**
Psychiatrics

**Street address**
Pasdaran Blv.

**City**
Sanandaj

**Province**
Kurdistan

**Postal code**
6617978743

**Phone**
+98 87 3366 4957

**Email**
nshamsalizadeh@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Sanandaj University of Medical Sciences

**Full name of responsible person**
Narges Shamsalizadeh

**Position**
associated professor

**Latest degree**
Medical doctor

**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Sanandaj University of Medical Sciences

**Full name of responsible person**
Narges Shamsalizadeh

**Position**
associated professor

**Latest degree**
Medical doctor

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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**
2 month

**Comments**