

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

inclusion: currently on antipsychotic medication; a score of at least 2 (mild akathisia) on the global subscale of the Barnes Akathisia Rating Scale (BARS) exclusion: taking betablocker, cyproheptadin, mianserin, B6 suicidal 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 on antipsychotic medication; a score of at least 2 (mild akathisia) on the global subscale of the Barnes Akathisia Rating Scale (BARS)

Exclusion criteria:

taking betablocker, cyproheptadin, mianserin, Vitamin B6 suicidal thought severe 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 allocation random 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

آکاتیژیا

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 questionnaire

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

Psychiatrics

Street address

Pasdaran Blv.

City

Sanandaj

Province

Kurdistan

Postal code

6617978743

Phone

+98 87 3366 4957

Email

nshamsalizadeh@yahoo.com

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

Other areas of specialty/work

Psychiatrics

Street address

Pasdaran Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6617978743

Phone

+98 87 3366 4957

Email

nshamsalizadeh@yahoo.com

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