

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The effect of trazodone on neuroleptic-induced acute akathisia

Protocol summary

Study aim

The Efficacy of Trazadone on Acute Neuroleptic-Induced Akathisia:

Design

double blind, randomised controlled trial

Settings and conduct

Patient on antipsychotic medication in Qods hospital

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, miancerin, B6 suicidal thought severe akathisia, global score of BARS >5

Intervention groups

In the intervention group, Trazodon 5 mg/d was prescribed. Similarly, the control group, received the placebo once daily for 5 day

Main outcome variables

akathisia, BARS score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191218045795N1**

Registration date: **2020-02-08, 1398/11/19**

Registration timing: **retrospective**

Last update: **2020-02-08, 1398/11/19**

Update count: **0**

Registration date

2020-02-08, 1398/11/19

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

2019-02-03, 1397/11/14

Expected recruitment end date

2019-07-14, 1398/04/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of trazodone on neuroleptic-induced acute akathisia

Public title

The effect of trazodone 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, miancerin, 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

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

4 - block allocationrandom

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

Pasdran Blv

City

Sanandaj

Province

Kurdistan

Postal code

6617978743

Approval date

2018-12-24, 1397/10/03

Ethics committee reference number

IR.MUK.REC.1397.310

Health conditions studied

1

Description of health condition studied

akathisia

ICD-10 code

ICD-10 code description

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 taking trazodon 50 mg\day for 5 day.preparations were available in identical capsules.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods hospital

Full name of responsible person

Zahra asadi

Street address

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Email

nshamsalizadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ibrahim Ghaderi

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Province

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Phone

+98 87 3366 4957

Email

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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 shams-alizadeh

Position

associated profesor

Latest degree

Medical doctor

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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Latest degree

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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

email : nshamsalizadeh@yahoo.com

What processes are involved for a request to access

data/document

2 month

Comments