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
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
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)
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Email address
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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 onantipsychotic medication; a score of at least 2(mild akathisia) on the global subscale of theBarnes Akathisia Rating Scale (BARS)
Exclusion criteria:
taking betablocker, cyproheptadin ,miancerin,B6 suiccidal 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 questionaire

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj 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 shams-alizadeh

Position

associated profesor

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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