Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effect of mirtazapine on anxiety in Parkinson’s disease patients; a randomized double-blinded placebo-controlled clinical trial

Protocol summary

Study aim
Evaluating the effect of mirtazapine on anxiety in Parkinson's patients

Design
This study is a single-center, parallel and double-blind study in Movement Disorders Clinic of Shohadaye Tajrish Hospital. Patients, researchers (physicians, outcome assessors) and data analysts are blinded. After assessing the inclusion and exclusion criteria’s, patients who assigned the informed consent form, are randomly divided into control and treatment groups.

Settings and conduct
Patients in treatment or placebo groups respectively receive mirtazapine (15 mg) or placebo, once a day for 12 weeks. Primary (anxiety) and secondary (depression, fatigue, sleep disorders, and quality of life) outcomes are evaluated at baseline, and after 4 and 12 weeks of treatments.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Men and women over 17 years old; Patient with Parkinson's disease according to UKPDSBB criteria; Patient with mild/moderate Parkinson’s disease according to Hoehn and Yahr Scale (HY score = 1-3); Self-report or clinical diagnosis of anxiety; Patients who have signed informed consent to participate in the study. Exclusion criteria: Pregnant and lactating women; Parkinson's patients with onset of disease in less than 1 year; Unstable medication for Parkinson's disease during the last two weeks; Parkinson's patients with DBS; Patients with other neurodegenerative diseases like multiple system atrophy (MSA), Huntington's and etc.; Patients with major depressive disorder; A history of using SSRIs, SNRIs, benzodiazepines and β-blockers during the last 4 weeks; A history of using MAO inhibitors; A history of alcohol and substance abuse; A history of acute stress during the last 3 months; A history of suicide; A history of cardiovascular diseases; A history of liver and or kidney disorders.

Intervention groups
Control (placebo) and mirtazapine groups

Main outcome variables
Anxiety score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191022045196N2**
Registration date: **2022-06-09, 1401/03/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-09, 1401/03/19**
Update count: **0**

Registration date
2022-06-09, 1401/03/19

Registrant information

Name
Neda Valian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-06, 1401/03/16

Expected recruitment end date
2024-06-05, 1403/03/16

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of mirtazapine on anxiety in Parkinson’s disease patients; a randomized double-blinded placebo-controlled clinical trial

Public title

Evaluating the effect of mirtazapine on anxiety in Parkinson’s disease patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women over 17 years old Patient with Parkinson's disease according to UKPDSBB criteria Patient with mild/moderate Parkinson’s disease according to Hoehn and Yahr Scale (HY score = 1-3) Self-report or clinical diagnosis of anxiety Patients who have signed informed consent to participate in the study

Exclusion criteria:

Pregnant and lactating women Parkinson's patients with onset of disease in less than 1 year Unstable medication for Parkinson's disease during the last two weeks Parkinson's patients with DBS Patients with other neurodegenerative diseases like multiple system atrophy (MSA), Huntington's and etc. Patients with major depressive disorder A history of using SSRIs, SNRIs, benzodiazepines and β-blockers during the last 4 weeks A history of using MAO inhibitors A history of alcohol and substance abuse A history of acute stress during the last 3 months A history of suicide A history of cardiovascular diseases A history of liver disorders A history of kidney disorders

Age

From **17 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method is used to divide the patients into placebo or drug groups. The patients will be assigned to placebo or drug groups (A and B) based on a random list prepared using SPSS software. For concealment, the placebo and drug are labeled as A and B, so patients and the researcher are unaware about the type of drug in each package.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, researchers (physicians, outcome assessors) and data analysts are not aware about prescribed drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Public Health and Neuroscience Research Center, Shahid Beheshti Univer

Street address

School of Public Health and Neuroscience Research Center, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Yaman Ave., Shahid Chamran Exp., Tehran, Iran

City

Tehran

Province

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Postal code

1983963113

Approval date

2022-01-04, 1400/10/14

Ethics committee reference number

IR.SBMU.PHNS.REC.1400.130

Health conditions studied

1

Description of health condition studied

Parkinson’s disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Anxiety score

Timepoint

Anxiety score at the baseline, and after 4 and 12 weeks of treatment

Method of measurement

Hamilton Anxiety Rating Scale (HAM-A) and Parkinson Anxiety Scale (PAS) questionnaires

Secondary outcomes

1

Description
Depression score
Timepoint
Depression score at the baseline, and after 4 and 12 weeks of treatment
Method of measurement
Hamilton Depression Rating Scale (HAM-D) questionnaire

2

Description
Fatigue score
Timepoint
Fatigue score at the baseline, and after 4 and 12 weeks of treatment
Method of measurement
Parkinson’s Disease Fatigue Scale (PDFS) questionnaire

3

Description
Sleep disorder score
Timepoint
Sleep disorder score at the baseline, and after 4 and 12 weeks of treatment
Method of measurement
Parkinson's disease Sleep Scale (PDSS) questionnaire

4

Description
Quality of life score
Timepoint
Quality of life score at the baseline, and after 4 and 12 weeks of treatment
Method of measurement
Parkinson's Disease Quality of Life (PDQL) questionnaire

Intervention groups

1

Description
Intervention group: Mirtazapine (15mg), once a day, for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo, once a day, for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Mehri Salari
Street address
Shohadaye Tajrish Educational Hospital, Tajrish Square, Tehran Tehran
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Sponsors / Funding sources

1

Sponsor
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mehri Salari

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Pharmacology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available