

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 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  $\beta$ -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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2242 9768

##### Email address

n.valian@sbmu.ac.ir

##### 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  $\beta$ -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

Tehran

##### 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

##### City

Tehran

##### Province

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##### Postal code

1989934148

##### Phone

+98 21 25719

##### Email

mehri.salari@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Leila Dargahi

##### Street address

Neuroscience Research Center, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Yaman Ave., Shahid Chamran Exp., Tehran

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##### Email

l.dargahi@sbmu.ac.ir

#### 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

l.dargahi@sbmu.ac.ir

### 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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Shohadaye Tajrish Hospital, Tajrish Square, Tehran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Leila dargahi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmacology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Neda Valian

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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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