

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparing safety and efficacy of melatonin, trazodone, and clonazepam on the sleep quality of patients with Parkinson's disease in patients referring to the Neurology Clinic of Roozbeh Hospital

Protocol summary

Study aim

Comparing safety and efficacy of melatonin, trazodone, and clonazepam on the sleep quality of patients with Parkinson's disease Best choice of drug to improve sleep quality in patients with Parkinson's disease

Design

This study is a double-blind clinical trial. Randomization method is a simple randomization. 30 people will be enrolled for each group. The study was performed for one month. Patients were randomly divided into three groups, each receiving either Melatonin or Trazodone or Clonazepam.

Settings and conduct

Patients with Parkinson's disease who have sleep disorder based on their medical history, who referred to the neurology clinic of Roozbeh Hospital, Tehran University of Medical Sciences, Tehran, Iran; enrolled in the study. Informed consent will obtain from all patients before inclusion into the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with Parkinson's disease who have sleep disorder based on their history. Exclusion criteria: A history of drug sensitivity, Hepatic failure Respiratory disorders or apnea, opioid user, cognition disorder and dementia, over 80 years old.

Intervention groups

Participants were randomly divided into 3 groups of 30 patients. 30 patients treated with 3 mg of melatonin, 30 patients treated with 50 mg of Trazodone, and 30 patients treated with 1mg of Clonazepam along with pre-existing Parkinson's medication. All trial drugs are administered at night before bedtime.

Main outcome variables

Sleep quality, Daytime sleepiness, REM sleep disorder

General information

Reason for update

According to the hospital research committee, the present trial and the IRCT20170821035819N3 trial were conducted simultaneously at Roozbeh Hospital by a same principle investigator in the form of a three-arm trial.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170821035819N2**
Registration date: **2020-01-29, 1398/11/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-29, 1400/09/08**

Update count: **1**

Registration date

2020-01-29, 1398/11/09

Registrant information

Name

Vajiheh Aghamollaii

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21554191515

Email address

v-aghamollaii@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-07-23, 1398/05/01

Actual recruitment end date

2020-09-12, 1399/06/22

Trial completion date

2020-10-25, 1399/08/04

Scientific title

Comparing safety and efficacy of melatonin, trazodone, and clonazepam on the sleep quality of patients with Parkinson's disease in patients referring to the Neurology Clinic of Roozbeh Hospital

Public title

Comparing safety and efficacy of melatonin, trazodone, and clonazepam on the sleep quality of patients with Parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Parkinson's disease who have sleep disorder based on history.

Exclusion criteria:

Dementia A history of drug sensitivity

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization Patients are divided into three treatment groups with 3 mg melatonin (A), 50 mg trazodone (B), and 1 mg clonazepam (C) using a simple random allocation method and a random number table. We referred "<https://www.graphpad.com/quickcalcs/randomize2/>" website for randomization, total sample size is 90 and were divided into three groups (A, B, C) each of them 30 patients. This is a randomized double-blind study. The drugs (Melatonin, Trazodone, and Clonazepam) are packaged in separate but similar packages and labeled A, B, and C on them. As a result, the patient is unaware of the type of drug in each package, and the analyst is also blinded. Method of administration: For the A group, 3 mg of Melatonin tablets are administered overnight (before bedtime). For the B group, 50 mg Trazodone is given overnight (before bedtime). For the C group, 1mg Clonazepam is given overnight (before bedtime).

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind study. The drugs are divided into groups A, B and C by a third person and given to the researcher. The researcher, participant and evaluator are unaware of the drug, until all data are fully analyzed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad Tehran Medical Sciences University - Pharmacy and Pharmaceutical Br

Street address

Doctor Shariati stereet, Qolhak

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IAU.PS.REC.1397.293

2**Ethics committee****Name of ethics committee**

Ethics committee of School of Medicine - Tehran University of Medical Sciences

Street address

Building no.1, Northern gate of the university, Poursina St. Qods St. Enqelab St.

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.094

Health conditions studied**1****Description of health condition studied**

Sleep disorder of patients with Parkinson's disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Sleep quality

Timepoint

First time and After 1 month

Method of measurement

Pittsburgh sleep quality questionnaire

2

Description

Daytime sleepiness

Timepoint

First time and After 1 month

Method of measurement

Epworth sleepiness score questionnaire

3

Description

Sleep Disorder

Timepoint

First time and After 1 month

Method of measurement

REM Sleep Behavior Disorder Screening Questionnaire (RBDSQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with Parkinson's disease who have sleep disorder, Take 3 mg Melatonin, once a night before bedtime, for one month (This drug is manufactured by Tehran Chemie Company)

Category

Treatment - Drugs

2

Description

Control group: Patients with Parkinson's disease who have sleep disorders, Take 50 mg Trazodone, once a night before bedtime, for one month (This drug is manufactured by Tehran Chemie Company)

Category

Treatment - Drugs

3

Description

Control group: Patients with Parkinson's disease who have sleep disorders, Take 1 mg Clonazepam, once a night before bedtime, for one month (This drug is manufactured by Tehran Chemie Company)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital Neurology Clinic, Tehran University of Medical Sciences

Full name of responsible person

Dr Vajiheh Aghamolaiy

Street address

Tehran Province, Tehran, District 11, Karegar St, No. 606

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 9151

Email

vajiheh102@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad-Ali Sahraeian

Street address

Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Vajiheh Aghamollaii

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Keshavarz Blvd.Rouzbeh Hospital, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21554191515

Fax

+98 21 5541 2756

Email

v-aghamolllai@sina.tums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Vajiheh Aghamollaii

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Kargar Sr

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 9151

Email

vajiheh102@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Vajiheh Aghamollaii

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Kargar Sr

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 9151

Email

vajiheh102@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

The Article will be publish in international journal and part of the data, such as information about the original outcome can shared without patients identification details.

When the data will become available and for how long

2020

To whom data/document is available

Published article will be available to everyone.

Under which criteria data/document could be used

Data will be made available to research organizations

and managers as needed.

From where data/document is obtainable

Dr Vajiheh Aghamollaii

What processes are involved for a request to access

data/document

Reason for request and affiliation person who requested data

Comments