

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Melatonin and Clonazepam on the REM sleep behavior disorder of patients with Parkinson's disease, a double blind randomized trial

Protocol summary

Study aim

Comparison of the effect of Melatonin and Clonazepam on REM 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. Patients were randomly divided into two groups, each receiving either melatonin or clonazepam.

Settings and conduct

Patients with Parkinson's disease who have REM sleep disorder based on results of a specific questionnaire or polysomnography, referred to the neurology clinic of Rouzbeh Hospital, 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 REM sleep disorder based on their history and questionnaire. Exclusion criteria: A history of drug sensitivity to clonazepam and either drug, Hepatic failure Respiratory disorders or apnea Opioid use Cognition disorder and dementia Over 65 years Old.

Intervention groups

Participants were randomly divided into two groups of 30 patients. 30 patients treated with 3 mg of Melatonin and 30 patients treated with 1 mg of Clonazepam, along with pre-existing Parkinson's medication. Both drugs are administered at night before bedtime. Melatonin starts at a dose of 3 mg and increases to 6 mg in the absence of appropriate response. Clonazepam is started at a dose of 0.5 mg and in the absence of appropriate response and no side effects after two weeks is increased to 1 mg.

Main outcome variables

Sleep quality Daytime sleepiness REM sleep disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170821035819N3**

Registration date: **2020-02-16, 1398/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-16, 1398/11/27**

Update count: **0**

Registration date

2020-02-16, 1398/11/27

Registrant information

Name

Vajiheh Aghamollaiy

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21554191515

Email address

v-aghaimollai@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

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of Melatonin and Clonazepam on the REM sleep behavior disorder of patients with Parkinson's disease, a double blind randomized trial

Public title
Comparison of the effect of Melatonin and Clonazepam on the REM sleep behavior disorder of patients with Parkinson's disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Parkinson's who have REM sleep disorder based on history and questionnaire
Exclusion criteria:
Dementia A history of drug sensitivity

Age
To **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization Patients were randomly divided into two groups of 30 patients, one group will be treated with 3 mg of Melatonin and another group will be treated with 1 mg of Clonazepam. We referred
"https://www.graphpad.com/quickcalcs/randomize2/" website for randomization, total sample size is 60 and were divided into two groups (A, B) each of them 30 patients. This is a randomized double blind study. The drugs (Melatonin and Clonazepam) are packaged in separate but similar packages and labeled A and B on them. As a result, the patient is unaware of the type of drug in each package, and the analyst is blind. Method of administration: For the A group, 3 mg of Melatonin tablets are administered overnight (before bedtime). For the B 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 and B by a third person and given to the researcher. The researcher, participant and analyzer 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 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
REM sleep behavior 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

REM 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 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

6th Floor, Qods Ave., Keshavarz Blvd.

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

Assistant Professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

South Kargar Sr

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 9151

Email

vajiheh102@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr 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

Dr 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

From 2020

To whom data/document is available

The Article will be available to everyone.

Under which criteria data/document could be used

Data will be made available to researchers, 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