Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of the effectiveness of Modafinil and methylphenidate in treatment of excessive daytime sleepiness in patients with Parkinson disease

Protocol summary

Study aim

Determining and comparing the mean changes of Epworth score after the intervention compared to before the intervention between the two groups of methylphenidate and medafinil Determining and comparing all the side effects reported during the study and comparing the rate of side effects between the two groups of medafinil or methylphenidate

Design

Clinical trial with 2 parallel randomized groups, double blinded, each group including 30 patients, Random allocation software was used for randomization.

Settings and conduct

The study will be performed on 60 patients with Parkinson's sisease who are randomly assigned to the medafinil or methylphenidate group. The study location is Isfahan University of Medical Sciences in Al-Zahra and Kashani Hospital in 1401. The study is double blinded. The two random groups are parallel. Blinding is done using randomly numbered drug containers. Participants, outcome checkers, observers, researchers, and data analyzers are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with Parkinson's disease. 2- Diagnosis of excessive daytime sleepiness by a neurologist 3-Insensitivity to modafinil or methylphenidate 4- The patient's consent to participate in the study Exclusion criteria: 1- Patient's dissatisfaction of participating in the study 2- History of head trauma 3- Diagnosis of other neurological diseases such as dementia 4- Stroke 5- Thyroid diseases 6- Substance abuser 7- Liver or kidney failure 8- Heart disease 9- History of psychiatric illness who is being treated with psychiatric drugs. 10- Taking hypnotics 11- Patient illiteracy

Intervention groups

One group is treated with medafinil and one group is treated with methylphenidate.

Main outcome variables

Evaluation of daily sleepiness using Epworth questionnaire before and after the intervention and recording of all side effects observed during the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220623055257N1**
Registration date: **2022-06-27, 1401/04/06**
Registration timing: **prospective**

Last update: **2022-06-27, 1401/04/06**
Update count: **0**

Registration date

2022-06-27, 1401/04/06

Registrant information

Name

Farzaneh Habibi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3071

Email address

fh1390i@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effectiveness of Modafinil and methylphenidate in treatment of excessive daytime sleepiness in patients with Parkinson disease

Public title

comparison of the effectiveness of Modafinil and methylphenidate in treatment of excessive daytime sleepiness in patients with Parkinson disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients who have Parkinson disease diagnosis of excessive daytime sleepiness(EDS) by neurologist not having sensitivity to Modafinil or Methylphenidate Individual consent to participate in the study

Exclusion criteria:

Dissatisfaction of the patient to continue participating in the study history of head trauma diagnosis of other neurological disease such as Dementia thyroid disorder history of CVA drug abuser kidney or liver failure heart disease History of a psychiatric illness being treated with psychiatric medication Taking hypnotics being illiterate

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants, clinicians, researchers, outcome evaluators, and data analysts do not know whether the patient is in the medafinil group or methylphenidate. The participant knows that he / she will be in one of these two groups, but the type of group is according to randomization methods. 60 patients are divided into two equal groups of 30 people according to random numbers generated by Random Allocation Software.The drug partner provides us with 60 boxes of exactly the same shape and weight that contain modafinil or methylphenidate. These drugs also look exactly the same, and these boxes are available to the participant according to random numbers produced by the software. At the end of the complete data analysis, our drug partner informs us what medicine each box contains.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, clinicians, researchers, outcome evaluators, and data analysts do not know whether the patient is in the medafinil group or methylphenidate. The participant knows that he will be in one of these two groups, but the type of group depends on the methods of randomization.Each participant receives a box containing methylphenidate or modafinil. These two types of boxes are completely similar in appearance. The method of allocating the box is according to numbers generated by randomization software.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib St., Ethics Committee of Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2022-04-23, 1401/02/03

Ethics committee reference number

IR.MUI.MED.REC.1401.030

Health conditions studied

1

Description of health condition studied

Daily-time sleepiness in patients with Parkinson's

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description
Daily sleepiness in patients with Parkinson's
Timepoint
Beginning of study and 8 weeks later
Method of measurement
Epworth Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 patients with Parkinson's disease who are treated with medafinil at a dose of 200 mg daily for 8 weeks to treat daily drowsiness.
Category
Treatment - Drugs

2

Description
Intervention group: 30 patients with Parkinson's disease who are treated with methylphenidate at a dose of 10 mg daily for 8 weeks to treat daily drowsiness.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital Clinic
Full name of responsible person
Farzaneh Habibi
Street address
Soffe Boulevard
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81746-73461
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Keyvan Basiri
Street address
Hezar Jarib Ave.
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Farzaneh Habibi
Position
Neurology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
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Person responsible for updating data

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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
No - There is not 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
Individual data of study participants

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic, scientific institutes

Under which criteria data/document could be used
Using data for review articles

From where data/document is obtainable
Researcher email address Farzaneh Habibi : fh1390i@yahoo.com

What processes are involved for a request to access data/document
Check the individual dependence on the university center

Comments