

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 modafinil Determining and comparing all the side effects reported during the study and comparing the rate of side effects between the two groups of modafinil 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 disease who are randomly assigned to the modafinil 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 modafinil 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 modafinil 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 modafinil 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**

Isfahan

**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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3792 3071

##### Email

fh1390i@yahoo.com

## 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.

#### City

Isfahan

#### Province

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#### Postal code

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#### Phone

+98 31 3792 3071

#### Email

fh1390i@yahoo.com

#### 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

##### Street address

Hezar Jarib Ave, Isfahan university of Medical Sciences

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## Person responsible for scientific 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**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Farzaneh Habibi

**Position**

Neurology Resident

**Latest degree**

Medical doctor

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**Fax****Email**

fh1390i@yahoo.com

## 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**