

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### Evaluation of the efficacy of Methylphenidate and modafinil in the treatment of excessive daily sleepiness in patients with drug-resistant epilepsy and comparison with the control group

#### Protocol summary

##### Study aim

Evaluation of the efficacy of Methylphenidate and Modafinil in the treatment of excessive daily sleepiness in patients with drug-resistant epilepsy and comparison with the control group

##### Design

A clinical trial with a parallel group and control group, double-blind, randomized

##### Settings and conduct

In this study, a history of patients with refractory epilepsy who have been referred to the hospital clinic for EDS complaints is selected and patients who meet the inclusion criteria are selected. EDS diagnosis is also performed using the EPWORTH sleepiness scale form. Patients are randomly divided into three groups. The first group is treated with methylphenidate, the second group is treated with modafinil and the third group is untreated for 8 weeks. The dose of methylphenidate will be 10-20-day / mg. Patients will also be treated with modafinil at a dose of 200-600 mg / day. Patients will be re-evaluated after the course of treatment by the EPWORTH sleepiness scale and the rate of recovery will be monitored.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People with refractory epilepsy; Diagnosis of EDS by a neurologist; Hypersensitivity to methylphenidate and modafinil; Individual consent to participate in the study; Exclusion criteria: Head trauma; Diagnosis of other neurologic diseases such as dementia; Stroke; Thyroid diseases; Drug abuse; Liver or kidney failure

##### Intervention groups

The first group is treated with methylphenidate, the second group is treated with modafinil and the third group is untreated for 8 weeks.

##### Main outcome variables

The amount of drowsiness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171030037093N22**

Registration date: **2019-10-18, 1398/07/26**

Registration timing: **prospective**

Last update: **2019-10-18, 1398/07/26**

Update count: **0**

##### Registration date

2019-10-18, 1398/07/26

##### Registrant information

##### Name

Sadra Ansari pour

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3650 3487

##### Email address

st\_ansari.s@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-25, 1398/08/03

##### Expected recruitment end date

2019-12-24, 1398/10/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
Evaluation of the efficacy of Methylphenidate and modafinil in the treatment of excessive daily sleepiness in patients with drug-resistant epilepsy and comparison with the control group

**Public title**  
Evaluation of the efficacy of Methylphenidate and modafinil in the treatment of excessive daily sleepiness in patients with drug-resistant epilepsy and comparison with the control group

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
People with refractory epilepsy Diagnosis of EDS by a neurologist Hypersensitivity to methylphenidate and modafinil Individual consent to participate in the study  
**Exclusion criteria:**  
Head trauma Diagnosis of other neurologic diseases such as dementia stroke Thyroid diseases Drug abuse Liver or kidney failure

**Age**  
No age limit

**Gender**  
Both

**Phase**  
1-2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **84**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The study sample was randomly divided into three groups of 28 each with a selection of closed envelopes. Each envelope containing one of the three labels A, B and C represented one of the groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The drugs were placed in envelopes in packages A and B without labeling and without the knowledge of the investigator.

**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

Isfahan University of Medical Sciences, Hezar jarib st, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

7346181746

##### Approval date

2019-09-14, 1398/06/23

##### Ethics committee reference number

IR.MUI.MED.REC.1398.327

## Health conditions studied

### 1

#### Description of health condition studied

Epilepsy

#### ICD-10 code

G40

#### ICD-10 code description

Epilepsy and recurrent seizures

## Primary outcomes

### 1

#### Description

The amount of drowsiness

#### Timepoint

Before and after treatment

#### Method of measurement

questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The first group will be treated with methylphenidate at 10-20-day / mg.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Group II treated with modafinil at a dose of 200-600 mg / day

#### Category

**3****Description**

Control group: The control group will be untreated for 8 weeks.

**Category**

Diagnosis

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Al-zahra hospital

**Full name of responsible person**

Mohammadreza Najafi

**Street address**

Sofe Blvd, Isfahan Province, Isfahan

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+98 31 3668 5555

**Email**

najafi@med.mui.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ziba Farajzadegan

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Isfahan University of Medical Sciences, Hezar jarib Avne

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farajzadegan@med.mui.ac.ir

**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**

Mohammadreza Najafi

**Position**

Professor of Neurology

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

Neurosciences Research Center, Al-Zahra Hospital, Isfahan University of Medical Sciences

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

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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**

No - There is not 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**

Yes - There is 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**

Information about the main outcome can be shared.

**When the data will become available and for how long**

Start the access period 4 months after publishing the results

**To whom data/document is available**

Researchers working in academia

**Under which criteria data/document could be used**

Use data to complete clinical trial studies

**From where data/document is obtainable**

Al-Zahra Hospital

**What processes are involved for a request to access data/document**

After the investigation of researcher request and presentation of required documents will be accessible.

**Comments**