Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 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

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Sadra Ansaripour

Name of organization / entity
Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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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
Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

City
Isfahan

Province
Isfehan

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

Treatment - Drugs

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ziba Farajzadegan
Street address
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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
Mohammadreza Najafi
Position
Professor of Neurology
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Professor of Neurology

Latest degree

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Other areas of specialty/work

Neurosurgery

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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