

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of methylphenidate on increasing the level of consciousness of patients with hypoxic ischemic encephalopathy in the special care departments of Bo Ali Qazvin Hospital during one year.

Protocol summary

Study aim

Investigating the effect of methylphenidate on increasing the level of consciousness of patients suffering from hypoxic ischemic encephalopathy

Design

A clinical trial with a control group, with parallel groups, double-blind, using placebo, randomized, phase 3 on 29 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Patients with hypoxic-ischemic encephalopathy in Bu-Ali hospital in Qazvin were included in the study by available sampling method, then the patients were blocked using random sampling method and assigned to one of the two study groups. In one group, methylphenidate 10 mg were given once a day and were combined with standard treatment, and the other group received only standard treatment. The level of consciousness in the patients was measured by the Four Score method and the vital signs in the patients of both groups were measured and its number was noted along with the hemodynamic indicators every three days during the patient hospitalization in the ICU .

Participants/Inclusion and exclusion criteria

Patients hospitalized in ICU; with the diagnosis of HIE; aged between 18 and 65 years; both sexes; with some degree of reduced level of consciousness.

Intervention groups

The first study group was given methylphenidate tablets 10 mg once a day in the morning until the day the patient stayed in the ICU (maximum one month) and the second study group was not given methylphenidate tablets.

Main outcome variables

Level of consciousness, duration of hospitalization in ICU.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220924056025N1**

Registration date: **2022-10-09, 1401/07/17**

Registration timing: **prospective**

Last update: **2022-10-09, 1401/07/17**

Update count: **0**

Registration date

2022-10-09, 1401/07/17

Registrant information

Name

Kian Abed khorasani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3350 4270

Email address

kianabed2495@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of methylphenidate on increasing the level of consciousness of patients with hypoxic ischemic encephalopathy in the special care departments of Bo Ali Qazvin Hospital during one year.

Public title

Investigating the effect of methylphenidate on increasing the level of consciousness in patients with hypoxic ischemic encephalopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients hospitalized in the intensive care unit with the diagnosis of HIE hypoxic ischemic encephalopathy, Aged between 18 and 65 years Both sexes (male and female) With some degree of reduced level of consciousness.

Exclusion criteria:

Patients with a history of epilepsy Patients with high blood pressure that is newly discovered and not treated or controlled Patients with Cardiac ischemia and arrhythmia that are newly discovered and not treated or controlled, Patients with deafness Patients with rapid changes in vital signs and unstable hemodynamics Patients with multiple organ failure Patients with hyperthyroidism pregnancy Drug addiction Secondary surgery Reluctance to attend the investigation based on the opinion of the patient's legal guardian

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are selected and included in the study using the available sampling method based on the entry and exit criteria. To assign patients to treatment groups, block randomization method is used so that the number of samples assigned to each of the two treatment groups is balanced. According to the sample size of 24 in each group, 12 blocks of 4 random permutations of two treatment methods A, B (in the form of AABB) are needed. Random allocation software version 2 is used to create random permutations of 4 (random blocks of 4). The output of the software is alternating random combinations of 4 of the two treatment methods, based on which the patients are assigned to one of the two treatment groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

A placebo is prepared by a pharmaceutical company similar to methylphenidate tablets at the request of the researcher. After that, the placebo and the drug are coded by a non-researcher observer, and the coded drugs are provided to the researcher. The drug code is provided to the researcher at the end of the study. . the standard treatment, while the patient nurse researcher does not know which group the patient is in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Qazvin University of Medical Science

Street address

No115,East406,Phase 4 Mehrshahr ,Karaj

City

Qazvin

Province

Qazvin

Postal code

3183834377

Approval date

2020-09-18, 1399/06/28

Ethics committee reference number

IR.QUMS.REC.1399.226

Health conditions studied

1

Description of health condition studied

Hypoxic ischemic encephalopathy

ICD-10 code

P91.6

ICD-10 code description

Hypoxic ischemic encephalopathy [HIE]

Primary outcomes

1

Description

Average level of consciousness based on 4 Score criteria

Timepoint

Every three days for a month

Method of measurement

Criterion 4 Score in ICU

Secondary outcomes

1

Description

Average biological indicators of systole and diastole blood pressure

Timepoint

Every three days for a maximum of one month

Method of measurement

Recording of ICU patient monitoring every three days for a maximum of one month

2

Description

Average biological index of arterial oxygen saturation percentage

Timepoint

Every three days for a maximum of one month

Method of measurement

Recording of ICU patient monitoring every three days for a maximum of one month

3

Description

Average biological index of heart rate

Timepoint

Every three days for a maximum of one month

Method of measurement

Recording of ICU patient monitoring every three days for a maximum of one month

Intervention groups

1

Description

Intervention group: this group receives 10 mg methylphenidate tablets once a day in the morning until the day the patient stays in the ICU (maximum one month) in the form of gavage.

Category

Treatment - Other

2

Description

Control group: The control group receives daily placebo in the form of gavage in the morning until the day the patient stays in the ICU (maximum one month).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Boali Qazvin Hospital ,ICU Dep

Full name of responsible person

Kian Abed Khorasani

Street address

Naderi st, Bo Ali Hospital,Qazvin

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3413786165

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+98 28 3333 2930

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin Medical Sciences Research Deputy

Full name of responsible person

Dr. Mehdi Mir Hashemi

Street address

Qazvin, Bahonar Ave, Qazvin University of Medical Sciences

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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

Qazvin Medical Sciences Research Deputy

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

Qazvin University of Medical Sciences

Full name of responsible person

Kian Abed Khorasani

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Kian Abed Khorasani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual data in accordance with the approval of the ethics committee Primary and secondary outcomes

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions Physicians working in the special care department of hospitals

Under which criteria data/document could be used

Contact to the researcher for determining the examples

From where data/document is obtainable

Dr. Kian Abed Khorasani, Qazvin University of Medical Sciences, contact number 09907485823, email kianabed2495@gmail.com

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

Direct contact with the researcher, investigation and response within a maximum of two weeks, in case of non-availability, contact with the Research Vice-Chancellor of Qazvin University of Medical Sciences

Comments