Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effect of Methylphenidate on consciousness in patients with brain damage in ICU

Protocol summary

Study aim
Evaluation of the effect of Methylphenidate on consciousness in patients with brain damage in intensive care unit

Design
This study is clinical trial and double blind.90 patients with brain damage in ICU in Valiasr Hospital in Arak will inter this study.We will divide patients in 2 groups by simple randomization.Groups are parallel.

Settings and conduct
This study is clinical trial and double blind.90 patients with brain damage in ICU in Valiasr Hospital in Arak will inter this study.Outcome assessor and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria:A level of consciousness less than 10, being intuitive Ages between 16 and 50 years, history of brain injury, absence of spacer lesion in brain scan (hematoma, tumor), no history of seizures, no addiction to psychotropic substances and drugs, no history of amphetamine use, no history of hypertension, ischemic heart disease and diabetes mellitus, heart rate less than 120 times per minute Exclusion criteria: seizure, arrhythmia, death

Intervention groups
Intervention group: Patients will receive 0.3 milligram in kilogram methylphenidate daily in two divided doses of 6 morning and 2 afternoon. Control group: Patients will not receive anything.

Main outcome variables
Level of consciousness, severity of illness, duration of ventilation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N128**
Registration date: **2020-01-10, 1398/10/20**
Registration timing: **retrospective**

Last update: **2020-01-10, 1398/10/20**
Update count: **0**

Registration date
2020-01-10, 1398/10/20

Registrant information

Name
Fariba Farokhi

Name of organization / entity
Arak 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
2018-04-30, 1397/02/10

Expected recruitment end date
2019-12-31, 1398/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Methylphenidate on consciousness in patients with brain damage in ICU

Public title
Evaluation of the effect of Methylphenidate on

consciousness in patients with brain damage in ICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A level of consciousness less than 10 Being intuitive Ages between 16 and 50 years History of brain injury Absence of spacer lesion in brain scan (hematoma, tumor) No history of seizures No addiction to psychotropic substances and drugs No history of amphetamine use No history of hypertension, ischemic heart disease and diabetes mellitus Heart rate less than 120 times per minute

Exclusion criteria:

Seizure Arrhythmia Death

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in two groups A and B. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of Arak University of Medical Sciences

Street address

Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.ARAKMU.REC.1397.025

Health conditions studied

1

Description of health condition studied

Brain damage

ICD-10 code

P11.2

ICD-10 code description

Unspecified brain damage due to birth injury

Primary outcomes

1

Description

Level of consciousness

Timepoint

daily to clearance time

Method of measurement

Glasgow coma scale

2

Description

Illness severity

Timepoint

First and third day and time of discharge

Method of measurement

Apache score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive 0.3 milligram in

kilogram methylphenidate daily in two divided doses of 6 morning and 2 afternoon.

Category

Treatment - Drugs

2

Description

Control group: Patients will not receive anything.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Behnam Mahmodie

Street address

Valiasr Hospital, Valiasr squre, Shahid Shirodi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Medicine student

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General Practitioner

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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
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
When we publish article in journal

When the data will become available and for how long
After the article is published

To whom data/document is available
Researcher in university

Under which criteria data/document could be used
If there are additional questions

From where data/document is obtainable
Dr Behnam Mahmodie

What processes are involved for a request to access data/document
They have to write letters to the professors and the university

Comments