

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### 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 committee of Arak University of Medical Sciences

##### **Street address**

Ethics committee, Research center, Payambar Azam complex, Basij square, 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 squire, Shahid Shirodi street

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Email**

mahmodie@arakmu.ac.ir

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

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Arjmandzadegan

**Street address**

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3222 2003

**Fax**

+98 86 3222 2003

**Email**

arjmandzadegan@arakmu.ac.ir

**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

**Street address**

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 68 3222 2003

**Fax**

+98 86 3222 2003

**Email**

alikalamiir@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Behnam Mahmodie

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

**City**

Arak

**Province**

Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Email**  
mahmodie@arakmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Anahita Kishani  
**Position**  
Medicine student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Vice chancellor for research, Payambar Azam  
Complex, Basij square, Sardasht, Arak  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Fax**  
+98 86 3222 2003

**Email**  
akishani319@gmail.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

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