

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Evaluation of methylphenidate on level of conciseness and hospital length of stay in patients with severe and moderate acute traumatic brain injury

#### Protocol summary

##### Study aim

Evaluation of methylphenidate effect on level of conciseness and hospital length of stay in patients with severe and moderate traumatic brain injury

##### Design

Randomization method: Blocks with multiples of 2 and different sizes based on a table of random numbers  
Sample size: Based on the same study , Considering the mean and standard deviation of the difference in the amount of accommodation in the special ward in the two groups of Ritalin and placebo equal to 2.5 and 3.5, the sample size in each group is 31 people . Two groups and 31 people in each group

##### Settings and conduct

Imam Khomeini Hospital, Sari-Individuals with eligibility criteria to enter the study after completing the form of conscious moral satisfaction of the book by block randomization method are assigned to the two groups. Multiple block size of 2 and different In a block, half of the people will be assigned to each of the study groups and the adjustment of the block size is done by randomization software and by an epidemiologist. The mentioned settings are covered for other researchers.

##### Participants/Inclusion and exclusion criteria

Inclusive Criteria: Moderate to severe brain injury and level of consciousness (GCS) between 5 and 12 that do not require surgery. Exclusive Criteria: 1. Children under 15 2. Adults over 75 years 3. Very severe trauma, especially in the chest and abdomen 4. Death in the first 48 hours 6. History of untreated heart disease or uncontrolled hypertension 7. Patients with unstable vital signs (fever above 39 degrees - uncontrolled infectious disease - hypotension - acute renal failure and high creatinine ..) 8. Emergency craniotomy

##### Intervention groups

Moderate to severe brain damage and level of consciousness (GCS) between 5 and 12 that do not

require surgery.

##### Main outcome variables

level of conciseness ; hospital length of stay

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140915019185N3**

Registration date: **2020-09-22, 1399/07/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-22, 1399/07/01**

Update count: **0**

##### Registration date

2020-09-22, 1399/07/01

##### Registrant information

##### Name

kaveh haddadi

##### Name of organization / entity

mazandaran university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 1058

##### Email address

k.haddadi@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2021-09-23, 1400/07/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of methylphenidate on level of conciseness and hospital length of stay in patients with severe and moderate acute traumatic brain injury

**Public title**  
Evaluation of methylphenidate on level of conciseness and hospital length of stay in patients with severe and moderate acute traumatic brain injury

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Moderate to severe brain damage and level of consciousness (GCS) between 5 and 12 that do not require surgery.  
**Exclusion criteria:**  
Children under 15 Adults over 75 years Very severe trauma accompanied by especially chest and abdomen Death in the first 48 hours History of untreated heart disease or uncontrolled hypertension Patients with unstable vital signs (fever above 39 degrees - uncontrolled infectious disease - hypotension - acute renal failure and high creatinine ..) Emergency craniotomy

**Age**  
From **15 years** old to **75 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **62**

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

**Randomization description**  
Blocks with multiples of 2 and different sizes based on a table of random numbers: Blocks with a multiple of 2 and different sizes based on the table of random numbers: Individuals with eligibility criteria to enter the study after completing the form of conscious moral satisfaction of the book by block randomization method are assigned to the two groups. Multiple block size of 2 and different In a block, half of the people will be assigned to each of the study groups and the adjustment of the block size is done by randomization software and by an epidemiologist. The mentioned settings are covered for other researchers.

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

**Blinding description**  
The placebo is designed by a pharmacologist. Due to the same shape and time of use of the drug and the placebo, the patient and the therapist do not know the type of drug.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics Committee of Mazandaran University of Medical Sciences

**Street address**  
Amir Mazandarani Imam Khomeini Hospital

**City**  
sari

**Province**  
Mazandaran

**Postal code**  
48166-33131

**Approval date**  
2020-06-24, 1399/04/04

**Ethics committee reference number**  
IR.MAZUMS.IMAMHOSPITAL.REC.1399.037

**Health conditions studied**

**1**

**Description of health condition studied**  
moderate and severe brain trauma

**ICD-10 code**  
S06.2X

**ICD-10 code description**  
Diffuse traumatic brain injury

**Primary outcomes**

**1**

**Description**  
level of conciseness

**Timepoint**  
the days 2,7 and discharge time

**Method of measurement**  
GCS

## Secondary outcomes

1

### Description

Delirium

### Timepoint

Day 2 and day 7 and at discharge

### Method of measurement

The incidence of delirium is first assessed by the RASS scale for level of consciousness and then by the CAM-ICU scale for delirium.

## Intervention groups

1

### Description

Patients with moderate to severe brain injury and level of consciousness (GCS) between 5 and 12 who do not have surgery for hemorrhagic lesion on CT scan. they will receive methylphenydaye.

### Category

Treatment - Drugs

2

### Description

Control group: Patients with moderate to severe brain injury and level of consciousness (GCS) between 5 and 12 who do not have SURGERY. they will receive placebo.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam Khomeini Hospital, Sari

#### Full name of responsible person

Kaveh Haddadi

#### Street address

Emam Khomeini hospital, Amir Mazandarani Ave

#### City

SARI

#### Province

Mazandaran

#### Postal code

48166-33131

#### Phone

+98 11 3336 1630

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#### Email

k.haddadi@mazums.ac.ir

#### Web page address

<https://www.mazums.ac.ir>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

Majid Saedi

#### Street address

Moalem Ave

#### City

SARI

#### Province

Mazandaran

#### Postal code

48157-33971

#### Phone

+98 11 3325 7230

#### Fax

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#### Email

m.saedi@mazums.ac.ir

#### Web page address

<https://www.mazums.ac.ir/>

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

#### Full name of responsible person

Kaveh Haddadi

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Neurosurgery

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#### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Kaveh Haddadi  
**Position**  
Associate professor  
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## Person responsible for updating data

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Mazandaran University of Medical Sciences

### Full name of responsible person

Kaveh Haddadi  
**Position**  
Associate professor  
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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available