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)

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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
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Web page address
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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
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Phone
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Fax
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Email
m.saedi@mazums.ac.ir
Web page 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
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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Person responsible for scientific inquiries

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Person responsible for updating data

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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