

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Methylphenidate on the Acute Management of Patients with Severe and Moderate Traumatic Brain Injury

Protocol summary

Summary

100 Severe and 100 Moderate consecutive traumatic brain injured patients admitted to Rajaei hospital (Shiraz, Iran) in the acute phase of recovery will be recruited into a randomized, double blind, placebo controlled trial. The patients will be divided into two groups of: severely brain injured and moderately brain injured patients. After which from each of the two groups a control group will be randomly selected. Methylphenidate and a placebo drug will be administered over a 2 week period for each of the groups. The treatment (case) group will receive methylphenidate 20 mg/kg per dose PO BID by the second day of admission until 2 weeks. Admission demographic information and also initial clinical evaluation results including: vital signs, injury severity score, CT findings, intracranial pressure monitoring (if performed), and daily Glasgow Coma Scale (GCS), will be recorded. Information regarding ICU and Hospital Stay, GCS, GOSE and DRS (disability rating score) on discharge and after 3 and 6 months will be recorded prospectively and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010112776N3**

Registration date: **2014-12-28, 1393/10/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-28, 1393/10/07

Registrant information

Name

Hosseinali Khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3625 4206

Email address

khalili_h@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research affairs of Shiraz University of Medical Sciences and Health Services

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Methylphenidate on the Acute Management of Patients with Severe and Moderate Traumatic Brain Injury

Public title

Effects of Methylphenidate on the Acute Management of Patients with Severe and Moderate Traumatic Brain Injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: ages between 16 and 60; having a history of non-penetrating traumatic brain injury with a GCS=6-8 (Severe) and GCS 9-12 (Moderate) without multi organ injury or failure. Exclusion criteria: not agreeing to enter the study; not being able to tolerate

nasogastric Feeding; dying in 48 hours of admission; having a history of pre-morbid neurologic disease, psychosis, major affective disorder, developmental disability, ADHD, currently abusing alcohol or recreational drugs. taking psychoactive medications other than anticonvulsants. having systemic diseases that could have affected the results eg. Diabetes or psychiatric problems, pregnancy or likely to become pregnant; mental retardation, behavioral problems, impairments in vision, hearing, or motor function that were severe enough to preclude participation in the research tasks.

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Vice-chancellor for Research affairs, at 7th floor,
Shiraz University of Medical Sciences, Zand Avenue,
Shiraz, Iran

City

Shiraz

Postal code

7194815644

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

CT-P-92-5276

Health conditions studied**1****Description of health condition studied**

Moderate and Severe Traumatic Brain Injury

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Cognitive function

Timepoint

During 3 and 6 months of follow-up

Method of measurement

Using cognitive measuring tests

Secondary outcomes**1****Description**

Lenght of ICU stay

Timepoint

Total ICU treatment duration

Method of measurement

Based on patients' file and record

2**Description**

Lenght of overall hospital stay

Timepoint

Total hospital treatment duration

Method of measurement

Based on patients' file and record

3**Description**

GCS

Timepoint

During 3 and 6 months of follow-up

Method of measurement

GCS specific tests

4**Description**

GOSE

Timepoint

During 3 and 6 months of follow-up

Method of measurement

GOSE specific tests

5**Description**

Disability Rating Score

Timepoint

During 3 and 6 months of follow-up

Method of measurement

DRS specific tests

Intervention groups

1

Description

Patients in the treatment(case) group will receive methylphenidate 20 mg/kg per dose PO BID by the second day of admission for two weeks.

Category

Treatment - Drugs

2

Description

Patients in the control group will receive placebo 20 mg/kg per dose PO BID by the second day of admission for two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajae Hospital

Full name of responsible person

Hossein Ali Khalili

Street address

Shiraz Neurosciences Research Center-Chamran
Hospital-Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Research affairs, Shiraz University of medical
Sciences, Zand Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz Neurosciences Research Center

Full name of responsible person

Hosseinali Khalili

Position

Neurosurgeon

Other areas of specialty/work

Street address

Chamran hospital N/S Dept

City

Shiraz

Postal code

Phone

+98 71 1623 4508

Fax

Email

khalilih16@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz Neurosciences Research Center

Full name of responsible person

Hosseinali Khalili

Position

Neurosurgeon

Other areas of specialty/work

Street address

Chamran hospital N/S Dept.

City

Shiraz

Postal code

Phone

+98 71 1623 4508

Fax

Email

khalilih16@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz Neurosciences Research Center

Full name of responsible person

Hosseinali Khalili

Position

Assistant Professor

Other areas of specialty/work

Street address

Chamran hospital N/S Dept.

City

Shiraz

Postal code

Phone

+98 71 1623 4508

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty