

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of coma induced by thiopental and propofol in Traumatic Brain Injury patients admitted in intensive care unit

Protocol summary

Study aim

Comparison of the effect of thiopental sodium and propofol on cerebral coma in patients with traumatic brain injury

Design

This study will be a double-blind randomized clinical trial with parallel groups on 60 patients with traumatic brain injury referred to Peymaniyeh Hospital in Jahrom. Patients participating in the study will be divided into two groups by tossing coins.

Settings and conduct

Patients with traumatic brain injury referred to Peymaniyeh Hospital in Jahrom will be included in the study. Patients participating in the study will be divided into two groups of propofol and sodium thiopental by tossing coins. The person participating in the study, the researcher and the data collector will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with traumatic brain injury in Peymanieh Hospital in Jahrom city with the full consent of the patient and his legal parents to participate in the study. Exclusion criteria: Pregnant patients will not be allowed to enter the study.

Intervention groups

Intervention group 1: Patients in the thiopental group in the intensive care unit will receive 2 mg per kg body weight of sodium thiopental bolus injection and a maintenance dose of 2 to 6 mg per kg body weight per hour. Intervention group 2: Patients in the propofol group in the intensive care unit will receive a bolus injection of propofol 0.5 mg per kilogram of body weight, followed by an injection of propofol 3 to 5.4 per kilogram of body weight per hour.

Main outcome variables

Induction of coma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050976N1**

Registration date: **2021-05-17, 1400/02/27**

Registration timing: **prospective**

Last update: **2021-05-17, 1400/02/27**

Update count: **0**

Registration date

2021-05-17, 1400/02/27

Registrant information

Name

navid kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 6085

Email address

k.navid@juma.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-10-02, 1400/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of coma induced by thiopental and propofol in Traumatic Brain Injury patients admitted in intensive care unit	
Public title	Comparison of the effect of coma induced by thiopental and propofol in Traumatic Brain Injury patients
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Satisfaction to participate in the study Consciousness level less than 8 according to Glasgow Coma Scale (GCS) Head injury without damage to other vital organs Full consent of the patient and his / her legal guardians to participate in the study
Exclusion criteria:	pregnancy
Age	From 20 years old to 60 years old
Gender	Both
Phase	2-3
Groups that have been masked	- Participant - Investigator - Outcome assessor
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Patients participating in the present study will be divided into two groups: propofol and sodium thiopental by tossing coins.
Blinding (investigator's opinion)	Double blinded
Blinding description	For blinding, in the present study, the double-blind method is used so that the person reviewing the results and the person performing the injections do not know which patients received propofol and which thiopental sodium. The syringes will be covered with black glue.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Jahrom University of Medical Sciences
Street address	Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research
City	jahrom
Province	Fars
Postal code	7167758256
Approval date	2021-03-09, 1399/12/19
Ethics committee reference number	IR.JUMS.REC.1399.149
Health conditions studied	
<u>1</u>	
Description of health condition studied	Patients with traumatic brain injury
ICD-10 code	S06.1X7
ICD-10 code description	Traumatic cerebral edema with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness
Primary outcomes	
<u>1</u>	
Description	Induction of coma
Timepoint	Before injection and then for three days (three times a day: morning, noon and night shifts)
Method of measurement	By bispectral index criteria
Secondary outcomes	
<u>1</u>	
Description	level of consciousness
Timepoint	Measure before injection and after injection daily (every 15 minutes) for 3 days
Method of measurement	Glasgow Criterion
<u>2</u>	
Description	Vital signs
Timepoint	Measure before injection and after injection daily (every 15 minutes) for 3 days
Method of measurement	Monitoring device

Intervention groups

1

Description

Intervention group 1: Patients in group 1 will receive sodium thiopental drug in the intensive care unit as a bolus of 2 mg per kg of body weight and a maintenance dose of 2 to 6 mg per kg of body weight per hour.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients in group two will receive propofol in the intensive care unit as a bolus of 5 mg per kg of body weight and a maintenance dose of 3 to 4.5 mg / kg of body weight per hour.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Peymaniyeh Hospital of Jahrom city

Full name of responsible person

Navid Kalani

Street address

Jahrom, Shahid Motahari Boulevard, Peymanieh Hospital

City

jahrom

Province

Fars

Postal code

71677251542

Phone

+98 71 3525 5652

Email

Navidkalani@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Peaceful Solh joo

Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

City

jahrom

Province

Fars

Postal code

7167758256

Phone

+98 71 2536 5231

Email

navidkalani@ymail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Jahrom University of Medical Sciences

City

jahrom

Province

Fars

Postal code

7167758256

Phone

+98 71 3525 5652

Email

Navidkalani@ymail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

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Anesthesiology

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Email

k.navid@jums.ac.ir

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

Person responsible for updating data**Contact****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Jahrom University of Medical Sciences

City

jahrom