Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Post intubation hemodynamic effects of intravenous lidocaine in patients with severe brain trauma

Protocol summary

Summary

Two groups of patients with head trauma conventional medical protocol before undergoing intubation (succinylcholine 1.5 mg / kg + rapid intravenous fentanyl 2 mg / kg + intravenous etomidate 0.3 mg / kg through IV) were are but one group in addition to the common protocol, the amount of lidocaine to intubating 1 mg / kg perfusion within 60-30 seconds will be used. Patients' vital signs such as heart rate, respiratory rate of systolic, diastolic and mean arterial (MAP) once before and once after intubation between the two groups of patients studied and the results are compared. Other variables such as need, GCS patients, the diagnosis Trmay such as EDH, SDH, SAH, and .... We will examine the main factors. It should be noted that the plans for trained nurses recorded patients' vital signs before and after intubation would be completely unaware of the protocol will be used for sedation intubation. The primary outcomes of the decrease in mean arterial pressure (MAP) and heart rate, and the secondary outcome was defined as the use of inotropic drugs or isotonic fluids.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042813150N1**
Registration date: **2013-05-08, 1392/02/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-05-08, 1392/02/18

Registrant information

Name

Mohammad.ali Najjari Asl

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

research vice-chancellor Tabriz University of Medical Sciences, Faculty of Medicine

Expected recruitment start date

2013-04-30, 1392/02/10

Expected recruitment end date

2013-07-07, 1392/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Post intubation hemodynamic effects of intravenous lidocaine in patients with severe brain trauma

Public title

Post intubation hemodynamic effects of intravenous lidocaine in patients with severe brain trauma

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: all patients aged 65-18 years with traumatic brain injury with GCS <9; patients who have been intubated prior to admission to the emergency room; before referring patients to the emergency room, and inotropic drugs have not received isotonic fluids.
Exclusion criteria: patients aged 18 years and above 65

year; patients with heart failure; in patients with shock, hypovolemia, sepsis and cardiogenic reason; patients with a previous history of heart disease and hypertension; start inotropic drugs before intubation and evidence of cardiac arrhythmia.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Tabriz Azadi Street - Street Golgasht - Central Building University of Medical Sciences - Tel 3355921-25 Fax: 3355944

City
Tabriz

Postal code

Approval date
2013-04-09, 1392/01/20

Ethics committee reference number
925

Health conditions studied

1

Description of health condition studied
Patients with severe head trauma

ICD-10 code
S06

ICD-10 code description
Intracranial injury

Primary outcomes

1

Description
Heart Rate

Timepoint
Once before and once after intubation

Method of measurement
by an automatic blood pressure cuff

2

Description
systolic Arterial pressure

Timepoint
Once before and once after intubation

Method of measurement
by an automatic blood pressure cuff

3

Description
Diastolic arterial pressure

Timepoint
Once before and once after intubation

Method of measurement
by an automatic blood pressure cuff

4

Description
mean arterial pressure

Timepoint
Once before and once after intubation

Method of measurement
by an automatic blood pressure cuff

Secondary outcomes

1

Description
The rate of use of isotonic fluids

Timepoint
After intubation

Method of measurement
Chart of Fluids

2

Description
The rate of use of inotropic agents

Timepoint
After intubation

Method of measurement
Chart of drugs

Intervention groups

1

Description
In the control group patients before intubation only common protocols (conventional pharmacological protocol for patients with head trauma (succinylcholine 1.5 mg / kg + rapid intravenous fentanyl 2 mg / kg + intravenous etomidate 0.3 mg / kg perfusion)), is used for intubation.
Category
Treatment - Drugs

2

Description
Intervention group patients before intubation in addition to standard protocols (conventional pharmacological protocol for patients with head trauma (succinylcholine 1.5 mg / kg + rapid intravenous fentanyl 2 mg / kg + intravenous etomidate 0.3 mg / kg as iv)), the amount of lidocaine to intubating 1 mg / kg, intravenous use within 60-30 seconds.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emergency Department of Imam Reza Hospital
Full name of responsible person
Dr Peyman Moharamzadeh
Street address
Emergency Department of Imam Reza Hospital
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research, Tabriz University of Medical Sciences, Faculty of Medicine
Full name of responsible person
Dr. Ali Meshkini
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research vice-chancellor Tabriz Faculty of Medicine.Tabriz Azadi Street - Street Golgasht - Central Building University of Medical Sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for research, Tabriz University of Medical Sciences, Faculty of Medicine
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
Tabriz University of Medical Sciences
Full name of responsible person
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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)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty