

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 41 1658 6302

Email address

ali_njr@yahoo.com

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

Street address

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

Dr mohammad Ali Najjari Asl

Position

Emergency Medicine Resident

Other areas of specialty/work

Street address

Emergency Department of Imam Reza Hospital

City

Tabriz

Postal code

Phone

+98 41 1658 6302

Fax

Email

ali_njr@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Peyman Moharamzadeh

Position

Assistant Professor - Emergency Medicine

Other areas of specialty/work

Street address

Emergency Department of Imam Reza Hospital

City

Tabriz

Postal code

Phone

+98 41 1334 7054

Fax

Email

moharramzadehp@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Najjari Asl

Position

Emergency Medicine Resident

Other areas of specialty/work

Street address

Emergency Department of Imam Reza Hospital

City

Tabriz

Postal code

Phone

+98 41 1658 6302

Fax

Email

ali_njr@yahoo.com

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