

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Outcome measurement of pre-hospital prescription of hypertonic sodium in head trauma patients with decreased level of consciousness.

Protocol summary

Study aim

Outcome measurement of pre-hospital prescription of hypertonic sodium in head trauma patients with decreased level of consciousness.

Design

The design of the study is a randomized clinical trial. The randomization method is blocked. Patients will be randomly divided into 2 groups based on 10 blocks. The sample size for each study group is 100.

Settings and conduct

In this study, all patients with head trauma referred to Firoozgar and Haft-e-Tir hospitals with reduced consciousness will be enrolled. Patients will be randomly divided into 2 groups based on 10 blocks. The sample size for each study group is 100. A total of 200 patients will be examined. Patients and data analyzer will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients over 18 years; head trauma patients with decreased level of consciousness. Exclusion criteria: pregnancy; intrusive trauma; burn; the distance between the injury and the ambulance will be more than 30 minutes.

Intervention groups

In intervention group, patients will be injected with 500 cc of hypertonic sodium (50 %) at the site of the accident to the hospital. In control group, patients will be injected with 500 cc of normal saline at the site of the accident to the hospital.

Main outcome variables

Level of consciousness; blood pressure; pressure inside the brain; Oxygen saturation level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151003024317N10**

Registration date: **2020-01-23, 1398/11/03**

Registration timing: **prospective**

Last update: **2020-01-23, 1398/11/03**

Update count: **0**

Registration date

2020-01-23, 1398/11/03

Registrant information

Name

Mahdi Rezai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8868 6772

Email address

rezaei.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-09, 1398/11/20

Expected recruitment end date

2020-05-09, 1399/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Outcome measurement of pre-hospital prescription of hypertonic sodium in head trauma patients with decreased level of consciousness.

Public title

Measurement of pre-hospital prescription of hypertonic in

patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years old Head trauma patients with decreased level of consciousness
Exclusion criteria:
Pregnancy Intrusive Trauma The distance between the injury and the ambulance will be more than 30 minutes
Burn

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks with 10 person. In each block, 5 individuals will be in intervention group and 5 will be in control group. A total of 20 blocks will be considered for sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
Data will be analyzed by person who is blind to study groups. The therapist and patients will also be unaware of the type of treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Highway
City

Tehran
Province
Tehran
Postal code
1449614535
Approval date
2019-04-07, 1398/01/18
Ethics committee reference number
IR.IUMS.REC.1398.340

Health conditions studied

1

Description of health condition studied
Head trauma
ICD-10 code
G44.31
ICD-10 code description
Acute post-traumatic headache

Primary outcomes

1

Description
Level of consciousness
Timepoint
At the scene, on arrival at the hospital, after the intervention
Method of measurement
Based on patient records

2

Description
Blood pressure
Timepoint
At the scene, on arrival at the hospital, after the intervention
Method of measurement
Based on patient records

3

Description
Pressure inside the brain
Timepoint
On arrival at the hospital, after the intervention
Method of measurement
Based on patient records

4

Description
Oxygen saturation level
Timepoint
On arrival at the hospital, after the intervention
Method of measurement
Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients will be injected with 500 cc of normal saline at the site of the accident to the hospital.

Category

Placebo

2

Description

Intervention group: patients will be injected with 500 cc of hypertonic sodium (50 %) at the site of the accident to the hospital.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar hospital

Full name of responsible person

Mahdi Rezai

Street address

Vali Asr Sq. Beh Afarin Ave.

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2

Recruitment center

Name of recruitment center

Shohada-e- Haftome tir Hospital

Full name of responsible person

Mahdi Rezai

Street address

Emergency Department, Shohada-e- Haftome tir Hospital, Shahid rajae Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mahdi Rezai

Position

Assistant Professor of Emergency Medicine

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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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