Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparison on effectiveness of Dexmedetomidine and Propofol on serum level of NSE and S100B in patients with traumatic brain injury

Protocol summary

Study aim
A comparison on effectiveness of Dexmedetomidine and Propofol on serum level of NSE and S100B in patients with traumatic brain injury

Design
A single center, double blind and randomized clinical trial with two parallel groups on 60 patients.

Settings and conduct
Traumatic brain injury patients admitted to ICU of Semnan Kowsar Hospital will be studied. Patients and care providers will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Traumatic Brain Injury patients, intubation in ICU, over 18 years old. Exclusion criteria: Massive bleeding, acute or chronic renal failure, acute or active liver disease, rheumatologic disorders or auto-immune disease, acute MI, hypersensitivity to drugs, egg and soya

Intervention groups
Intervention group 1: Will receive dexmedetomidine (precedex , Hospira, USA) 1 mcg/kg IV for intubation.
Intervention group 2: Will receive propofol (diprivan, Fresenius Kabi, Germany) 5 mcg/kg IV for intubation.

Main outcome variables
Neuron Specific Enolase (NSE) and S100 Calcium-Binding Protein (S100B)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200824048500N1**
Registration date: **2021-01-25, 1399/11/06**
Registration timing: **prospective**

Last update: **2021-01-25, 1399/11/06**
Update count: **0**

Registration date
2021-01-25, 1399/11/06

Registrant information
Name
Fateme Feizi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparison on effectiveness of Dexmedetomidine and Propofol on serum level of NSE and S100B in patients with traumatic brain injury

Public title
Effects of Dexmedetomidine and Propofol in brain injury patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Traumatic Brain Injury patients (TBI) Intubation In ICU

Over 18 years old

Exclusion criteria:

Massive bleeding Acute or chronic renal failure Acute or active liver disease Rheumatologic disorders or auto-immune disease Acute MI Hypersensitivity to drugs or egg and Soya

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two groups of intervention and control with 30 members using block randomization with block sizes of 2. Randomized permutation blocks (block 2). Excel software rand function was used for randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and researchers or outcome assessors are unaware of the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Basij Blvd , Semnan University of Medical Sciences

City

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Province

Semnan

Postal code

3514799442

Approval date

2020-07-28, 1399/05/07

Ethics committee reference number

IR.SEMUMS.REC.1399.146

Health conditions studied

1

Description of health condition studied

Traumatic brain patients

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Neuron Specific Enolase (NSE)

Timepoint

Before intervention and 24hr after intervention

Method of measurement

Elisa

Secondary outcomes

1

Description

S100 calcium-binding protein B (S100B)

Timepoint

Before intervention and 24hr after intervention

Method of measurement

Elisa

Intervention groups

1

Description

Intervention group 1: Will receive dexmedetomidine 1 mcg/kg IV for intubation.(precedex , Hospira , US)

Category

Treatment - Drugs

2

Description

Intervention group 2 : Will receive propofol (diprivan , Fresenius Kabi , Germany) 5 mcg/kg IV for intubation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Bahador Bagheri

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Semnan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information

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