

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 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 autoimmune 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3624 0902

Email address

fatemefeizi9775@gmail.com

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 autoimmune 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

Semnan

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.(precdex , 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

Street address

Kowsar Hospital, Amin Blvd., Basij Blvd., Semnan

City

Semnan

Province

Semnan

Postal code

3519637452

Phone

+98 23 3345 1336

Email

bagherib@semums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

Street address

Vice Chancellor for Research and Technology,
Semnan University of Medical Sciences, Basij Blvd.,
Semnan

City

Semnan

Province

Semnan

Postal code

35147-99442

Phone

+98 23 3345 1336

Email

p_kokha@yahoo.com

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

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Fateme Feizi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No 75, 5th Street, Sepah Avenue, Varamin

City

Varamin

Province

Tehran

Postal code

35147-99442

Phone

+98 21 3624 0902

Fax

Email

fatemefeizi9775@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Fateme Feizi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No 75,fifth street ,Sepah Ave,Varamin, Tehran

City

Varamin

Province

Tehran

Postal code

35147-99442

Phone

+98 21 3624 0902

Fax

Email

fatemefeizi9775@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Fateme Feizi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No 75,fifth street ,Sepah Ave,Varamin, Tehran

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Province

Tehran

Postal code

35147-99442

Phone

+98 21 3624 0902

Fax**Email**

fatemefeizi9775@gmail.com

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