# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The comparison of close and open tracheal tube suction on severity of pain and physiological indicators in patients under mechanical ventilation with traumatic brain injuries

## Protocol summary


**Summary**

The aim of this study is to compare the pain intensity and physiological variables during both open and closed suctions in patients with traumatic brain injuries. This study is a clinical trial. All patients with traumatic brain injuries in Kowsar Hospital in Semnan will form the study society. The main criterion for inclusion is the need for endotracheal suctioning. The most important exclusion criterion is pain before suctioning. The sample size is estimated to be 116. In this study patients are randomly divided into two groups and open and close suctions will be done crossly for them. When the patients undergo open suction, they are disconnected from the ventilator and suction will be performed using a catheter with a pressure less than -120 mm Hg for 14 seconds. When the patients undergo closed suction, they will not be disconnected from the ventilator and suction catheter is inserted via y-piece connector which is placed between endotracheal tube and ventilator tube and suction will be performed. In both groups and in both the first and second turns, pain, systolic and diastolic blood pressure, mean arterial blood pressure, heart rate, respiration rate, spo2 level and Etco2 will be recorded before the intervention, during the intervention and five minutes after it. Then the difference between the studied variable will be compared before and after the intervention.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016052311399N4**
Registration date: **2016-06-14, 1395/03/25**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2016-06-14, 1395/03/25

**Registrant information**


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Abbasali Ebrahimian

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**


**Funding source**

Vice chancellor for research, Semnan University of Medical Science


**Expected recruitment start date**

2016-06-21, 1395/04/01

**Expected recruitment end date**

2016-12-21, 1395/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The comparison of close and open tracheal tube suction on severity of pain and physiological indicators in patients under mechanical ventilation with traumatic brain injuries

**Public title**

The comparison of close and open tracheal tube suction on severity of pain and physiological indicators in

patients under mechanical ventilation with traumatic brain injuries

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: The Patient is placed under mechanical ventilation simply due to traumatic brain injuries or to subsequent secondary complications; The patient is in a coma and his GCS is less than 8; Endotracheal tube is used for patients in order to get airway; Endotracheal tube is merely through the mouth; They don't take pain medications; Their livers and kidneys do not have trauma in the latest incident; They don't take neuromuscular blockers; They need endotracheal tube secretion suctioning and patients don't have severe face injuries. Exclusion criteria: The patient is brain-dead; They need to regain their suction before two hours; The existence of dangerous cardiac arrhythmias in monitoring patients; Any pain before suctioning; The use of painkillers or drugs on the stimulation of the patient's upper airway secretions drainage and history of patients' CPR after hospitalization.

**Age**

From **35 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **116**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Crossover

**Other design features**

Patients will be divided into two groups by using sealed envelopes method.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethic committee of Semnan University Of Medical sience

**Street address**

Vice chancellor for research, Semnan University of Medical Sciences, Basij Blvd

**City**

Semnan

**Postal code**

**Approval date**

2016-05-25, 1395/03/05

**Ethics committee reference number**

IR.SEMUMS.REC.1395.31

## Health conditions studied

### 1

**Description of health condition studied**

Pain

**ICD-10 code**

R52.9

**ICD-10 code description**

Pain, unspecified

### 2

**Description of health condition studied**

physiological indicators

**ICD-10 code**

R62.8

**ICD-10 code description**

Other lack of expected normal physiological development

### 3

**Description of health condition studied**

Traumatic brain injuries

**ICD-10 code**

Intracrani

**ICD-10 code description**

S06.9

## Primary outcomes

### 1

**Description**

Pain

**Timepoint**

Before suctioning, during suctioning, 5 minutes after suctioning

**Method of measurement**

Critical-care pain objective tool

## Secondary outcomes

### 1

**Description**

Physiological indicators

**Timepoint**

Before suctioning, during suctioning, 5 minutes after suctioning

**Method of measurement**

Monitoring devices, pulse oximetry, recorded ETCo2

## Intervention groups

**1**

**Description**
Intervention group (1): Patient will receive 100% oxygen for two minutes by ventilator. Then the patient is disconnected from ventilator and suction will be done by sterile method from ventilator and using a catheter number 14 and the pressure less than 120 mm Hg for 14 seconds and consequently the patient's endotracheal tube is connected to ventilator again and he will be undergone 100% oxygen therapy by ventilator for two minutes.

**Category**
Other

**2**

**Description**
Intervention group (2): Patient will not be disconnected from the ventilator. In these patients the suction catheter goes through the endotracheal tube through Y-piece connector between endotracheal tube and ventilator tube and suction will be done. In these patients suction will be done by catheter suction for 14 seconds with -120 mm Hg.The patient will be undergone 100% oxygen therapy by ventilator before and after suction.

**Category**
Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Kowsar Hospital

**Full name of responsible person**
Dr Darush Pahlevan

**Street address**
1 th Floor, Vice chancellor for research, Kowsar Hospital, Basij Blvd

**City**
Semnan

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice chancellor for research, Semnan University of Medical Sciences

**Full name of responsible person**
Dr Ali Rashidi-Pour

**Street address**
Vice chancellor for research, Semnan University of Medical Sciences, Basij Blvd

**City**
Semnan

**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, Semnan University of Medical Sciences

**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

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**Name of organization / entity**
Semnan University of Medical Sciences

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Msc in critical care nursing

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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*