

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 suction 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 suction 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

Name

Abbasali Ebrahimian

Name of organization / entity

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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 science

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

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

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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

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

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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Position

Msc in critical care nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

PhD of Health in Emergencies and Disasters

Other areas of specialty/work

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Position

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Postal code**Phone****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