Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Comparing the clinical outcomes of the T-piece and pressure support ventilation among patients with head trauma: a randomized controlled clinical trial

Protocol summary

Study aim
Compare the clinical outcomes of T-piece and pressure support ventilation among patients with traumatic brain injury.

Design
The present study was a randomized clinical trial with control group on 60 patients

Settings and conduct
This study is performed in the intensive care unit of Shahid Rajaee hospital in Qazvin. There was no blinding in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: at least 18 years old of age; Patients undergoing mechanical ventilation for more than 48 hours and less than 2 weeks; Glasgow coma scale (GCS) equal to or greater than 9; Normal electrolytes; Hemoglobin greater than 8; Body temperature less than 38.5. Non-inclusion criteria: Chronic cardiopulmonary problems; Use of vasoactive drugs; Spinal cord injury; Seizure; Decreased consciousness due to toxicity.

Intervention groups
Intervention group: T-piece group. Patients are weaned from the mechanical ventilation device and will be placed under ventilation with T-piece for 2 hours. If they tolerate spontaneous breathing, successful weaning will be occurred and otherwise it will be failure in weaning. Control group: Pressure support ventilation group. Patients will be placed on spontaneous ventilation mode with pressure support of less than 8 cm of water. If they tolerate spontaneous breathing, successful weaning will be occurred and otherwise it will be failure in weaning.

Main outcome variables
Weaning of mechanical ventilation, extubation, length of mechanical ventilation, length of hospital stay, mortality rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171212037848N3**
Registration date: **2020-04-06, 1399/01/18**
Registration timing: **retrospective**

Last update: **2020-04-06, 1399/01/18**
Update count: **0**

Registration date
2020-04-06, 1399/01/18

Registrant information

Name
Sareh Mohammadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the clinical outcomes of the T-piece and pressure support ventilation among patients with head trauma: a randomized controlled clinical trial

Public title
Investigating the Effect of Using the T-pieace Method among patients with head trauma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients hospitalized in intensive care units Received mechanical ventilation for at least 48 hours and at most two weeks Age of more than 18 years old Glasgow Coma Scale (GCS) score of more than 9 Normal electrolyte levels Hemoglobin greater than 8 Body temperature less than 38.5

Exclusion criteria:
chronic disease and cardiopulmonary problem intake of vasoactive medications spinal cord injury history of convulsion Poisoning-induced altered consciousness

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly allocated to the intervention and a control groups through block randomization method using blocks of size 4.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences

Street address
Bahonar boulevard

City
Qazvin

Province
Qazvin

Postal code
1531534199

Approval date
2020-03-19, 1398/12/29

Ethics committee reference number
IR.QUMS.REC.1398.388

Health conditions studied

1

Description of health condition studied
Head trauma patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Weaning of mechanical ventilation

Timepoint
During the hospital stay

Method of measurement
Examine the vital signs of the patient

2

Description
Extubation

Timepoint
During the hospital stay

Method of measurement
Examine the vital signs of the patient

3

Description
Duration of mechanical ventilation

Timepoint
After the weaning of mechanical ventilation

Method of measurement
Number of days the patient is under mechanical ventilation

4

Description
Length of hospital stay

Timepoint
Weaning time until hospital discharge

Method of measurement
Number of days of hospitalization

5

Description
Death rate

Timepoint
Time of death
Method of measurement
Number of deaths in two groups

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients in the intervention group were placed on the T-piece for two hours. Patients who did not tolerate spontaneous breathing were reconnected to MV , were considered as unsuccessful weaning, and were subjected to another weaning attempt 24 hours after the first attempt. Spontaneous breathing toleration criteria were respiratory rate of less than 35 per minutes, heart rate of less than 140 beats per minute, arterial oxygen saturation of more than 90%, arterial partial oxygen pressure of more than 60 mm Hg, and no symptom of increased respiration workload such as sweating, dyspnea, and use of accessory respiratory muscles . Patients who fulfilled the criteria of spontaneous breathing for two hours were considered as successful weaning and were subjected to extubation. After extubation, patients who did not need re-intubation for 48 hours were considered as successful extubation
Category
Treatment - Other

2

Description
Control group: In the control group, patients who fulfilled weaning criteria were placed on pressure support ventilation (PSV) with a pressure support of less than 8 mm Hg. If patients tolerated spontaneous breathing for two hours were considered as successful weaning and were subjected to extubation; otherwise, they were considered as unsuccessful weaning and placed on synchronized intermittent mandatory ventilation (SIMV). Patients with successful weaning and extubation were considered as successful extubation if they did not need re-intubation during the first 48 hours after extubation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee Hospital
Full name of responsible person
Sareh Mohammadi
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Sponsors / Funding sources

1

Sponsor
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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
Qazvin 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
Qazvin University of Medical Sciences
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Position
MSc in Nursing and Intensive Care
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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 a decision to publish the article.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available