# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 28 3333 6001

**Email address**
s.mohammadi@qms.ac.ir

**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
**Street address**
Shahid Bahonar boulevard
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3441734313
**Phone**
+98 28 3289 9470
**Email**
sareh_mohammadi@ymail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Mohammad Mahdi Emamjomeh
**Street address**
Bahonar boulevard
**City**
Qazvin
**Province**
Qazvin
**Postal code**
15315-34199
**Phone**
+98 28 3333 6001
**Email**
info@qums.ac.ir
**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
**Full name of responsible person**
Sareh Mohammadi
**Position**
MSc in Nursing and Intensive Care
**Latest degree**
Master

**Other areas of specialty/work**
Others
**Street address**
Bahonar boulevard
**City**
Qazvin
**Province**
Qazvin
**Postal code**
15315-34199
**Phone**
+98 28 3333 6001
**Email**
sareh_mohammadi@ymail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Sareh Mohammadi
**Position**
Master's degree nursing specialist
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
Shahid Bahonar boulevard
**City**
Qazvin
**Province**
Qazvin
**Postal code**
15315-34199
**Phone**
+98 28 3333 6001
**Fax**
**Email**
s.mohammadi@qms.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Sareh Mohammadi
**Position**
Master's degree nursing specialist
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
Shahid Bahonar boulevard
**City**
Qazvin
**Province**
Qazvin
**Postal code**
15315-34199
**Phone**
+98 28 3333 6001
**Fax**
**Email**
s.mohammadi@qms.ac.ir

## 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