Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of assessment of the readiness of weaning of head trauma patients from mechanical ventilation device on the duration of mechanical ventilation and duration of hospitalization

Protocol summary

Study aim

Determining the effect of using the weaning tool on the duration of mechanical ventilation and duration of hospitalization.

Design

In this study, 60 patients admitted to the ICU ward, who have had mechanical ventilation for more than 48 hours and have criteria for entering the study, selected by easy sampling and divided into two groups of control and intervention using a 4-block method.

Settings and conduct

This study is a randomized controlled clinical trial. After approval by Ethics Committee and taking informed consent from patients' family, the study begin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients with head injuries -At least 18 years old - Patients under mechanical ventilation for more than 48 hours and less than 2 weeks - Not having heart disease and other underlying disease - GCS above 9 Exclusion criteria: -Spontaneous removal of tracheal tube during the study -Surgery during the study - Transferring the patient to other wards -Having a failure history in weaning

Intervention groups

In the control group, the patient is weaning from the mechanical ventilation device according to the ward routine and the gradual reduction of the number of ventilator breathing and insertion of the patient into the spont mode, is done.In the intervention group, under ventilation patients will be scored based on Persian weaning tool in each shift (q 8 hr.), this score ranks between 26 to 75, If patients get a score of 57 and above, process of weaning will begin under observation of an anesthesiologist and patient is placed on the t-piece.

Main outcome variables

-Mechanical ventilation duration -During hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171212037848N2**
Registration date: **2018-10-27, 1397/08/05**
Registration timing: **retrospective**

Last update: **2018-10-27, 1397/08/05**
Update count: **0**

Registration date

2018-10-27, 1397/08/05

Registrant information

Name

Sareh Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-20, 1396/12/29

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2018-03-20, 1396/12/29

Actual recruitment end date

2018-09-22, 1397/06/31

Trial completion date

2018-09-22, 1397/06/31

Scientific title
Effect of assessment of the readiness of weaning of head trauma patients from mechanical ventilation device on the duration of mechanical ventilation and duration of hospitalization

Public title
The effect of evaluation of weaning preparation from ventilator on duration of hospitalization and duration of mechanical ventilation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who were under mechanical ventilation for more than 48 hours
Exclusion criteria:
Patients without an endotracheal tube
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be controlled and intervened by randomization 4-way blocking method
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Performing a type of intervention on the test group

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Approval date
2017-12-01, 1396/09/10
Ethics committee reference number
14002724

Health conditions studied

1

Description of health condition studied
Head traumatic patients undergoing mechanical ventilation
ICD-10 code
S06.2
ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Duration of mechanical ventilation and duration of hospitalization
Timepoint
48 hours after the extubation
Method of measurement
Persian weaning Tool

Secondary outcomes

1

Description
Hospital costs
Timepoint
After the patient's discharge
Method of measurement
Calculate direct patient costs

Intervention groups

1

Description
Intervention group:Patients with mechanical ventilation over 48 hours who received the criteria for entry with a Persian weaning tool. If they get 57, the patient will be weaning from the mechanical ventilation device. If it can be breathable with T-piece for 2 hours, the weaning will be successful and these patients will be compared with the control group according to the number of mechanical ventilation days and hospitalization duration.
Category
N/A

2

Description
Control group: Head trauma patients who had mechanical ventilation for more than 48 hours and had criteria for entering the study and were routinely weaning from the mechanical ventilation device

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaee hospital in Qazvin

Full name of responsible person
Sareh Mohammadi

Street address
Qazvin University of Medical Sciences, No. 456,Gargani Street ,Padegan Street, Shahid Rajaee Hospital, Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr. Amir Peimani

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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

Full name of responsible person
Sareh Mohammadi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Master's degree nursing specialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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