

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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

Email address

s.mohammadi@qms.ac.ir

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
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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

Contact

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Sareh Mohammadi

Position

Master's degree nursing specialist

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Person responsible for updating data

Contact

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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