Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Determining and comparing the effect of two airway humidification systems on respiratory parameters and arterial blood gases among head-trauma patients under the aggressive mechanical ventilation

Protocol summary

Study aim
Analyzing the effect of two airway humidification systems on respiratory parameters and arterial blood gases

Design
Cross over clinical trial

Settings and conduct
First, after identifying the patients that met the inclusion criteria, the head nurse of the department used numbers' random tables (randomization) to divide the patients into two intervention groups of one and two. Then, the experienced nursing staff in the department, they were unaware of the objectives and results of the study (blinded study), used one of the airway humidifiers in the intervention group one for 30 minutes, and another airway humidifier for the intervention group two for 30 minutes. At the end of 30 minutes and having recorded the results (respiratory parameters and sending arterial blood gas samples and obtaining the result) in case of the lack of the risk factors for the patient, such as, dramatic and abnormal changes in results of arterial blood gases and in hemodynamic changes and in the absence of critical medical condition, the two humidification devices were interchanged in the intervention groups one and two, and they were used for 30 again, then the results were recorded as the first stage.

Participants/Inclusion and exclusion criteria
The patients with decreased level of consciousness after a trauma were admitted to the intensive care unit and were required invasive mechanical ventilation

Intervention groups
1. Based on the random number table, the eligible patients are assigned to the first group and one of the airway humidification devices is applied to the group, randomly. 2. The eligible patients are assigned to the second group randomly; one of the airway humidification devices is applied to the group, randomly

Main outcome variables
Respiratory parameters and parameters of arterial blood gas

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20180906040961N1**
Registration date: **2018-10-17, 1397/07/25**
Registration timing: **na**

Last update: **2018-10-17, 1397/07/25**
Update count: **0**

Registration date
2018-10-17, 1397/07/25

Registrant information

Name
Ahmad Shahvandary

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3835 8258

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afgoudarzi@kums.ac.ir

Recruitment status
Not enough for processing

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2018-12-21, 1397/09/30

Actual recruitment start date
2018-09-23, 1397/07/01
Actual recruitment end date
2018-09-13, 1397/06/22
Trial completion date
2018-12-22, 1397/10/01

Scientific title
Determining and comparing the effect of two airway humidification systems on respiratory parameters and arterial blood gases among head-trauma patients under the aggressive mechanical ventilation

Public title
Analyzing the effect of two airway humidification systems on respiratory parameters and arterial blood gases
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with head trauma Patients with decreased level of consciousness Patients with mechanical ventilation Patients with no chest trauma Patients with no acute or chronic lung disease Patients with no history of acute or chronic kidney failure Not to be a brain death Not to be an organ transplant candidate The normality of the analysis of arterial blood gas results No hypothermia No bleeding in the airway
Exclusion criteria:
The patient’s parents’ unwillingness to participate in the study Patient with critical medical condition To be in a dying condition Brain death confirmation Organ transplant candidate Patient’s death
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **53**
More than 1 sample in each individual
Number of samples in each individual: **4**
Respiratory parameters and arterial blood gases after using each airway humidifiers
Randomization (investigator's opinion)
Randomized
Randomization description
12- After identifying the research samples, because of 8 beds in the unit, the patient are categorized into two groups by the chief nurse.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features
Determining and comparing the effect of two airway humidification systems on respiratory parameters and arterial blood gases among head-trauma patients under the aggressive mechanical ventilation

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Kermanshah University of Medical Sciences, Faculty of Nursing and Midwifery
Street address
Shahid Beheshti Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6714673159
Approval date
2018-07-23, 1397/05/01
Ethics committee reference number
IR.KUMS.RES.1397.235

Health conditions studied

1

Description of health condition studied
Effect of airway humidifiers on the respiratory parameters and arterial blood gases
ICD-10 code
X
ICD-10 code description
Diseases of the respiratory system

Primary outcomes

1

Description
The amount to respiratory parameters and parameters of arterial blood gases before using airway humidifiers
Timepoint
Immediately after starting intervention
Method of measurement
Using respiratory data of patient by ventilator and analysis of arterial blood gases

Secondary outcomes

1

Description
The amount to respiratory parameters and parameters of

arterial blood gases after using airway humidifiers

Timepoint

30 minutes after using each airway humidifier

Method of measurement

Using respiratory data of patient by ventilator and analysis of arterial blood gases

Intervention groups

1

Description

Intervention group: The eligible patients of the study are divided into two groups – namely; the first and the second group- according to the random number table; one of the airway humidification devices is used randomly as an intervention for the first group, for 30 minutes, then the results are recorded and the second airway humidification software is used for 30 minutes and its results are recorded as well

Category

Treatment - Devices

2

Description

Intervention group: One of the airway humidification devices is used randomly for 30 minutes as an intervention for the eligible patients of the study who are placed in the second group according to the random number table, then the results are recorded and the second airway humidification software is used for 30 minutes and its results are recorded as well. In fact, we have an intervention group that is randomly divided into two groups, and both airway humidification devices are used randomly in a crossover manner, each for 30 minutes

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Ali Kosari

Street address

Farvardin Street, Neurosurgery ICU of Ahvaz Golestan Hospital

City

Ahvaz

Province

Khouzestan

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

50- Dr. Fardi Najafi

Street address

Shahid Beheshti Blvd

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

54- Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Ahmad Shahvandary

Position

M.Sc. Student in Nursing – ICU

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Ahmad Khoshay

Position

Member of Nursing and Midwifery Faculty

Latest degree

Specialist

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Position

M.Sc. Student in Nursing – ICU

Latest degree

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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

All Right Reserved to Kermanshah University of Medical Sciences

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data will be shared after making the participants' information unidentifiable

When the data will become available and for how long

It will be accessible six months after publishing results

To whom data/document is available

All researchers

Under which criteria data/document could be used

To use in the systematic review studies

From where data/document is obtainable

Kermanshah University of Medical Sciences

What processes are involved for a request to access data/document

Presenting request and receiving confirmation letter from university

Comments