Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of applying and non-applying of pain control algorithm on physiologic indexes and weaning in patients hospitalized in intensive care units

Protocol summary

Study aim

The effect of applying pain control algorithm on physiologic indexes and weaning in patients hospitalized in intensive care units

Design

In this research, 396 eligible patients being under mechanical ventilation in intensive care units of Ahvaz Golestan and Emam Khomaini hospitals will be chosen. Patients will be allocated to two equal groups of intervention and control groups using blocking randomization method.

Settings and conduct

This intervention study without blinding and two groups of intervention and control will be conducted on intensive care units of Ahvaz Golestan and Emam Ghomaini hospitals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having level of consciences between 3-5 based on Glasgow Coma Scale; having airway or tracheostomy tubes; being under mechanical ventilation using synchronized intermittent mandatory ventilation mode without intake of muscle relaxants; ability to move at least one of limbs; having stable hemodynamic. Exclusion criteria: having severe face injuries; inability for verbal communication; being under mechanical ventilation more than 48 hours; having smoking and cigarettes addiction; suffering from cancers; sensitivity to Morphine and Fentanyl drugs; intake of muscle relaxants using intermittent infusion; having renal and liver diseases.

Intervention groups

In intervention group, firstly morphine will be injected with dosage of 0.1 milligram per weight using bolus method. Then, 30 minutes after injection, pain and physiological indices will be assessed and recorded. If the pain will be more than 5, a single dosage of Morphine will be injected again using bolus, and 30 minutes after injection pain and physiological indices will be assessed and recorded again. Pain and physiological indices will be assessed and recorded each 60 minutes until obtaining of pain score less than 5, and after that each 4 hours until complete weaning of patient from ventilator. In control group, drug will be administer based on hospital routine, and one hour after intervention pain and physiological indices will be assessed and recorded again. Further assessment will be done based on nursing diagnosis. If the pain will be less than 5, then daily assessment for weaning will be implemented in both groups.

Main outcome variables

Pain, physiologic indexes and weaning

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170829035984N1**
Registration date: **2018-01-03, 1396/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-03, 1396/10/13**
Update count: **0**

Registration date

2018-01-03, 1396/10/13

Registrant information

Name

Zahra Karimi

Name of organization / entity

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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date
2017-07-23, 1396/05/01
Expected recruitment end date
2018-05-22, 1397/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of applying and non-applying of pain control algorithm on physiologic indexes and weaning in patients hospitalized in intensive care units

Public title
The effect of applying pain control algorithm on physiologic indexes and weaning
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having level of consciences between 3-5 based on Glasgow Coma Scale Having airway or tracheostomy tubes Being under mechanical ventilation using synchronized intermittent mandatory ventilation mode without intake of muscle relaxants Ability to move at least one of limbs Having stable hemodynamic
Exclusion criteria:
Having severe face injuries Inability for verbal communication Being under mechanical ventilation more than 48 hours Having smoking and cigarettes addiction Suffering from cancers Sensitivity to Morphine and Fentanyl drugs Intake of muscle relaxants using intermittent infusion Having renal and liver diseases
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: **396**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be allocated to groups using blocking randomization method.
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 Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan
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Province
Khouzestan
Postal code
6135715794
Approval date
2017-07-08, 1396/04/17
Ethics committee reference number
IR.AJUMS.REC.1396.350

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
M79.6
ICD-10 code description
Pain in limb

2

Description of health condition studied
Weaning from ventilator status
ICD-10 code
Z99.11
ICD-10 code description
Dependence on respirator [ventilator] status

3

Description of health condition studied
Physiological indices
ICD-10 code
R09.89
ICD-10 code description
Other specified symptoms and signs involving the circulatory and respiratory systems

Primary outcomes

1

Description
Pain
Timepoint
Before and after drug intervention
Method of measurement
Behavioral pain scale

2

Description
Physiological indices
Timepoint
Before and after drug intervention
Method of measurement
Researcher made checklist

3

Description
Weaning form ventilator
Timepoint
Daily
Method of measurement
Researcher made checklist

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description
Intervention group: Pain and physiological indices (heart rate, diastolic and systolic blood pressures, respiratory rate, and level of arterial oxygen saturation) of patients will be assessed and recorded in three shift works each 4 hours. If the pain will be more than 5, then nurse should alleviate pain with pain control algorithm. Firstly Morphine with dosage of 0.1 milligram per weight will be injected using bolus, and 30 minutes after injection pain and physiological indices will be assessed and recorded. If the pain will be more than 5, a single dosage of Morphine will be injected again using bolus, and 30 minutes after injection pain and physiological indices will be assessed and recorded again. Pain and physiological indices will be assessed and recorded each 60 minutes until obtaining of pain score less than 5, and after that each 4 hours until complete weaning of patient from ventilator. If the pain will be less than 5, then daily assessment for weaning will be implemented.
Category
Treatment - Drugs

2

Description
Control group: Pain and physiological indices (heart rate, diastolic and systolic blood pressures, respiratory rate, and level of arterial oxygen saturation) of patients will be assessed and recorded in three shift works each 4 hours. If the pain will be more than 5, then nurse should alleviate pain without pain control algorithm based on hospital routine. One hour after intervention pain and physiological indices will be assessed and recorded again. Further assessment will be done based on nursing diagnosis. If the pain will be less than 5, then daily assessment for weaning will be implemented.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Golestan hospital
Full name of responsible person
Zahra Karimi
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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
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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
Vice chancellor for research of Ahvaz Jundishapur 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
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Ahvaz Jundishapur University of Medical Sciences
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Only a part of patients demographical data and main outcomes will be shared.
When the data will become available and for how long
Six months after data publishing
To whom data/document is available
Data will be available only for researchers working on academic and university associations.
Under which criteria data/document could be used
Mention of study name and authors name
From where data/document is obtainable
Zahra Karimi: School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
What processes are involved for a request to access data/document
At last one month after request
Comments