

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 Khomainsi 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 Ghomainsi 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

Ahvaz Gundishapur University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3336 7543

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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

City

Ahvaz

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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Golestan hospital, Golestan road, Ahvaz, Khozestan

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Recruitment center

Name of recruitment center

Ahvaz Emam Khomeini hospital

Full name of responsible person

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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

Dr. Behzad Sharif Makhmalzadeh

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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**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Zahra Karimi

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Web page address

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