Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of implementing pain control instructions on sedation and duration of mechanical ventilation in patients admitted to the intensive care unit of Hakim Jorjani Hospital in 2020

Protocol summary

Study aim

Determining the effect of implementing pain control instructions on sedation and duration of mechanical ventilation in patients admitted to the intensive care unit of Hakim Jorjani Hospital in 2020

Design

Clinical trial with control group,With parallel,Non-blind,Randomized,Groups on 40patients

Settings and conduct

In the intensive care unit of Hakim Jorjani Hospital in Gorgan.Patients who are on Constant positive pressure or Spontaneous mode are evaluated according to pain control guidelines.The patient's sedation is interrupted,Fentanyl(1micrograms per kilogram per hour) infused as needed.After 4 hours,the patient is evaluated according to a Burn checklist.When a score above17 is obtained,The separation is performed as follows:Injection of a dose of intravenous dexamethasone,Application of one hour of oxygen 6to7 liters per minute on the T-piece,If tolerated if the endotracheal tube,after oxygenated,The tube is removed and if Having a truck,the administration of oxygen is interrupted by a T-piece.The patient is constantly monitored to connect to the ventilator if needed and to be among the unsuccessful cases;If tolerated,It will be one of the successful cases.

Participants/Inclusion and exclusion criteria

Inclusion criteria:having a endotracheal tube or tracheostomy, need for a ventilator,score higher than3 Richmond scale,score 5to13 of the Glasgow scale.Exclusion Criteria:Having kidney disease,Allergy to Morphine and Fentanyl

Intervention groups

Intervention group:Pain control instructions, pain behavioral scale and Richmond relaxation scale are performed and if sedation is needed according to these tools.according to the Bern checklist,separation from the ventilator is done according to the protocol.Control group:No additional drugs or placebo are administered

Main outcome variables

Pain control;Sedation;Duration of mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210906052394N1**
Registration date: **2021-10-18, 1400/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-18, 1400/07/26**
Update count: **0**

Registration date

2021-10-18, 1400/07/26

Registrant information

Name

Maryam Zarei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4332 3916

Email address

maryam.zareia1369@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of implementing pain control instructions on sedation and duration of mechanical ventilation in patients admitted to the intensive care unit of Hakim Jorjani Hospital in 2020

Public title

Implementation of pain control instructions on sedation and duration of mechanical ventilation in patients admitted to the intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a endotracheal tube or tracheostomy tube Need for mechanical ventilation Inability to communicate verbally Insensitivity to Morphine and Fentanyl No kidney disease Having a systolic blood pressure greater than 100 mm Hg A score above 3 on the Richmond scale A score between 5 Up to 13 on the Glasgow scale

Exclusion criteria:

Allergy to Morphine and Fentanyl Having kidney disease Score below 3 on the Richmond Scale Having a systolic blood pressure of less than 100 mm Hg

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

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

Islamic Azad University, Chalous Branch

Street address

Shahid Amini alley ,60 metri Ave,Emam Ali Blvd

City

Marvdasht

Province

Fars

Postal code

7371753519

Approval date

2020-09-08, 1399/06/18

Ethics committee reference number

IR.IAU.CHALUS.REC.1399.019

Health conditions studied

1

Description of health condition studied

Pain Control

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Sedation

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Mechanical Ventilation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain control

Timepoint

Consecutively every 4 hours after starting the study

Method of measurement

Behavioral tools for measuring pain(BPS)

2

Description

Sedation

Timepoint

Consecutively every 4 hours after starting the study

Method of measurement

Richmond agitation sedation acale

3

Description

Duration of mechanical ventilation

Timepoint

Consecutively every 4 hours after starting the study

Method of measurement

BURNS' WEAN ASSESSMENT PROGRAM (BWAP)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient is evaluated every 4 hours according to the Pain Control Instruction. If the patient needs pain relief (pain assessment with Pain Behavioral Scale), morphine 1 to 5 mg is used intravenously and Repeat every 10 minutes if needed. Maximum to 10 milligram per kilogram per hour is used. If the patient is not relieved with this amount of drug, it is evaluated using the Richmond sedation criterion and if necessary, 1 to 4 milligram of midazolam is injected intravenously. Repeat every 15 minutes if needed. Maximum to 10 milligram per houre can be used. At the threshold of separation from the mechanical ventilation device, the patient's sedation is discontinued and if necessary, fentanyl is infused at a dose of 1 micrograms per kilogram per hour. 4 hours after separation from the mechanical ventilator, using the Bern checklist, if a patient scores above 17, we use a single dose of intravenous dexamethasone (0.1 milligram per kilogram).

Category

Behavior

2

Description

Control group: "The control group continues to receive sedations as directed by the physician and does not receive any additional medications or placebos.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Jorjani Hospital, Gorgan

Full name of responsible person

Maryam Zarei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Scientific Association of Islamic Azad University, Aliabad Katoul Branch

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?

No

Title of funding source

Islamic Azad University, Aliabad Katoul Branch

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Maryam Zarei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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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
There is no more information.
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