Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of the effect of pain management program based on critical care pain observation tool (CPOT) on pain intensity and dose adjustment of analgesic in patients with decreased level of consciousness admitted to the intensive care units of Imam Reza Hospital in Mashhad .

Protocol summary

Study aim
The effect of implementing critical care pain observation tool on patient pain management with decreased level of consciousness admitted to the intensive care units

Design
A clinical trial study with parallel intervention and control groups, single-blinded, randomized.

Settings and conduct
This RCT is performed on 70 patients admitted to the ICU of Imam Reza Hospital who have decreased LOC and are receiving sedative infusions. At first, patients' restlessness is measured using the Richmond instrument. Then, in the intervention group, based on the CPOT instrument, the level of patients' pain is measured in two modes of rest and procedure, and based on this, the nurse adjusts the dose of analgesic drug. But in the control group, pain is assessed based on physiological indicators and the dose of analgesic is adjusted based on it. The dose of analgesics received and the severity of pain (based on the Behavioral Pain Scale tool) will be recorded at the end of the shift in research forms.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 18-65 years, Pulmonary patients, Inability to communicate verbally, systolic blood pressure>100 mmHg and a MAP> 65, Richmond score (-3≤RASS≤-1), At least 24 hours intubation and mechanical ventilation, using infusions of sedatives, Exclusion Criteria: The patient with drug, alcohol and psychotropic abuse, The patients with psychological disorders or history of epilepsy, patients with neuromuscular disease, patients with severe structural disorders of brain, Allergy to sedatives (fentanyl, morphine).

Intervention groups
In the intervention group, the dose of analgesics is adjusted based on the amount of pain assessed by the CPOT tool, and in the control group, the dose of analgesics is adjusted based on a 20% increase in each of the basic vital signs.

Main outcome variables
Dose of received analgesics

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201222049801N1**
Registration date: **2021-04-14, 1400/01/25**
Registration timing: **prospective**

Last update: **2021-04-14, 1400/01/25**
Update count: **0**

Registration date
2021-04-14, 1400/01/25

Registrant information

Name
Fatemeh Kouhi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-10, 1400/02/20

Expected recruitment end date
2021-09-21, 1400/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of pain management program based on critical care pain observation tool (CPOT) on pain intensity and dose adjustment of analgesic in patients with decreased level of consciousness admitted to the intensive care units of Imam Reza Hospital in Mashhad .

Public title
Evaluation of the effect of pain management program based on critical care pain observation tool (CPOT) on pain intensity and dose adjustment of analgesic in patients with decreased level of consciousness admitted to the intensive care units of Imam Reza Hospital in Mashhad .
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years Pulmonary patients subgroup (COPD, pneumonia, asthma, etc.) Inability to communicate verbally Having a systolic blood pressure greater than 100 mm Hg and a MAP> 65 Earn a score less than or equal to -1 and equal to or greater than -3 on the Richmond scale(-3≤RASS≤-1) At least 24 hours intubation and mechanical ventilation The need to use infusions of sedatives in the treatment program Admitted in the intensive care unit
Exclusion criteria:
The patient with drug, alcohol and psychotropic abuse The patients with psychological disorders or history of epilepsy The patients with neuromuscular disease The patients with severe structural problems of the brain Allergy to sedatives (fentanyl, morphine)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients' assignment into two groups will be based on their ward. By simple random method, we select the required number of units as the intervention groups. The remaining units will also be assigned as the control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are blinded about their group and the scale for pain measurment/sedative dosage. The statistcal analyzer is not aware about patient grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Qureishi Builsing, Daneshgah Ave. Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9184898885
Approval date
2021-02-09, 1399/11/21
Ethics committee reference number
IR.MUMS.NURSE.REC.1399.101

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
G89
ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Level of Pain
Timepoint
Before procedure and then 5, 15, 30 minutes after the procedures
Method of measurement
using critical care pain observation tool (CPOT) and (Behavioral Pain Scale) BPS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: At first, nurses measure the restlessness of patients based on the Richmond Instrument (RASS) to assess baseline status. Then, they measure the patient's pain before and after painful procedures (venipuncture, ABG test, change position, etc.) after 5, 15 and 30 minutes. The nurses will adjust the dose of prescribed sedatives based on the assessed pain. If CPOT = 3-5, intravenous fentanyl is given at 25 mcg per hour, and at CPOT = 6-8, intravenous fentanyl is given at 50 mcg per hour. This process will be done in 6 hours.

Category
Other

2

Description
Nurses evaluate the level of pain based on the routine process of the unit, which includes physiological indicators (heart rate, respiratory rate, systolic and diastolic blood pressure, SPO2) before and 5, 15, and 30 minutes after the procedure (venipuncture, ABG test, etc.). Then, based on a 20% increase in each of the basic vital signs, such as heart rate or blood pressure, etc., they adjust the prescribed sedatives in the range determined by the physician.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Fatemeh Kouhi

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School of Nursing and Midwifery, Ibn-e-Sina Ave. Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

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Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Kouhi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
No More information.

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
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable