

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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 ($-3 \leq \text{RASS} \leq -1$), 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)

Phone

+98 51 3729 3016

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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 measurement/sedative dosage. The statistical 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

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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.
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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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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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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