

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of analgesia-sedation protocol on pain, agitation and cardiovascular response of trauma patient in the surgical intensive care unit

Protocol summary

Study aim

Determining the effect of analgesic-sedative protocol on pain, restlessness and cardiovascular response of trauma patients

Design

Pain intensity, restlessness twice a day with Behavior Pain Scale , Behavioral Pain Scale-Non Intubated , numeric rating scale , Richmond Agitation Sedation Scale and delirium Use of Confusion Assessment Method- intensive care unit will be collected once a day during these 4 days.

Settings and conduct

Patients (General intensive care unit 3, 2 and 1) of Khorramabad Shohada Ashayer Hospital are screened sequentially and randomly assigned to two groups of protocol and control: Classes are built based on gender, age and severity of trauma (a total of 8 floors) and in each permutation blocks are used to be assigned . And the above blocks use a table of random numbers.

Participants/Inclusion and exclusion criteria

Admission requirements: trauma patients; Minimum time to connect or disconnect the fan 24 hours; Willingness to participate in the study; Able to self-report pain or express pain behaviors; Awareness level equal to or higher than 7; minimum intensive care unit admission time 48 hours; No pregnancy; No coagulation disorders. Conditions of non-entry: transfer to home and plant life palliative care unit, quadriplegia and the need for continuous infusion of nerve blockers; Deep sedation for alcohol withdrawal and active seizures, permanent brain damage; Final stage of renal and hepatic failure; Heart failure; Neurovascular injury, burns, ear, nose and throat,

Intervention groups

Pain intensity, restlessness twice a day with Behavior Pain Scale , Behavioral Pain Scale-Non Intubated , numeric rating scale , Richmond Agitation Sedation Scale and delirium Use of Confusion Assessment Method-

intensive care unit will be collected once a day during these 4 days.

Main outcome variables

Pain intensity; Restlessness; Cardiovascular response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150919024080N17**

Registration date: **2020-08-26, 1399/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

Registration date

2020-08-26, 1399/06/05

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of analgesia-sedation protocol on pain, agitation and cardiovascular response of trauma patient in the surgical intensive care unit

Public title

Effect of analgesia-sedation protocol on pain, agitation and cardiovascular response of trauma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Trauma patients (abdominal, chest, orthopedics trauma, and etc.) Patients need a ventilator with a minimum duration of 24 hours connected to the ventilator. Patients separated from the ventilator The minimum duration of separation from the ventilator is 24 hours. Willingness to participate in the study. Being able to self-report pain or express pain behaviors. level of consciousness equal and above 7 The minimum length of hospital stay in the ICU should be 48 hours. No pregnancy. No coagulation disorders

Exclusion criteria:

Transfer to home and using palliative care unit (end of life). Plant life, quadriplegia and the need for continuous infusion of nerve blockers and inhaled prostacyclins. Deep sedation to quit alcohol. Need for continuous infusion of sedative or analgesic for more than 24 hours. Patients with permanent brain injury admitted to neurosurgery wards. Deep sedation for treatment of active seizures. Patients in the final stage of kidney and liver failure. Cardiac arrest. Neurovascular injury, burns, ear, nose and throat surgeries, maxillofacial surgery, or plastic surgery to place a flap on the head or neck.

AgeFrom **18 years** old to **89 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample sizeTarget sample size: **84****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients were assigned to two groups of protocol and control based on stratified random sampling method. Classes were also made based on gender, age group and severity of trauma (a total of 8 classes) and within each class random permutation blocks were used to assign

patients to two groups. A table of random numbers is also used to construct the above blocks.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients participating in the study, pain examiners who included two trained nurses and also data analysts are not aware of the allocation of participants in the control and protocol groups. Due to the nature of the study and prescribing of the drug, the prescribing nurse and the coordinator or consultant of the research team (specialist in pain medicine and intensive care) were aware of the allocation of samples.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Lorestan Medical Sciences Ethics Committee

Street address

Lorestan, Khorramabad, Lorestan University of Medical Sciences, Campus Kamalvand, Vice Chancellor for Research and Technology

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Province

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Postal code

381351698

Approval date

2020-08-05, 1399/05/15

Ethics committee reference number

IR.LUMS.REC.1399.088

Health conditions studied**1****Description of health condition studied**

trauma

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes**1****Description**

Pain intensity in trauma patients in special surgical wards

Timepoint

Twice a day at 8-10 and 18-16 hours for a maximum of 4 days

Method of measurement

Behavioral Pain Scale BPS-NI, BPS, NRS Pain Numerical Scale

2

Description

Severity of restlessness in trauma patients in surgical wards

Timepoint

Twice a day at 8-10 and 18-16 hours for a maximum of 4 days

Method of measurement

Richmond Scale (RASS)

3

Description

Incidence of delirium in trauma patients in special surgical wards

Timepoint

Once a day for 18-16 hours for a maximum of 4 days

Method of measurement

CAM-ICU scale

Secondary outcomes

1

Description

Cardiovascular response of trauma patients in surgical special wards

Timepoint

Before and after each drug intervention

Method of measurement

Blood pressure with Blood pressure monitor and pulse monitoring with cardiac and respiratory monitoring with manual count in one minute

Intervention groups

1

Description

Intervention group: In the protocol (intervention) group, first, a comprehensive examination of the patient was performed. After, the patient entered the ward, simultaneously vital signs (blood pressure, pulse, respiration) using chart form, GCS, the disease severity using APACHE II tool, incidence and severity of pain using BPS BPS - NI, NRS tools and the level of restlessness were checked and recorded using RASS tool every 1-4 hours. Patients were divided into three groups with mild relief, severe relief and normal relief, based on the initial comprehensive assessment. Then the implementation of the protocol started. Before the implementation of the protocol, patients were checked in terms of probable problems including the need for tracheal tube suction, urinary catheter control for urinary retention, and also

being in the right position. If restlessness persisted, despite the above non-pharmacological interventions, based on the pain intensity and level of restlessness according to the protocol, an analgesic or sedative was prescribed intravenously / intramuscularly by the nurse in consultation with the intensive care physician (head of department). After drug administration, reassessment of pain and restlessness of the patient based on the desired instruments (BPS, BPS-NI, NRS and RASS) was performed every hour according to the protocol. In the implementation of the protocol, giving priority to the pain ladder, prescribing analgesics over sedatives, intermittent administration of analgesics or sedatives (bolus prescriptions), over continuous administration and also prescribing lighter sedative levels than heavier sedative levels (deep) and non-steroidal anti-inflammatory drugs were targeted. The dose of bolus was administered with an interval of 5 minutes. The maximum dose of bolus was three doses and if necessary, according to re-evaluations, the dose of continuous infusion was during 60 minutes. If pain or restlessness was not controlled with bolus doses, continuous infusions were started with the same analgesic or sedative drugs used as bolus (e.g., in fentanyl bolus, continuous fentanyl infusion, and in midazolam bolus, continuous midazolam infusion, etc.). Of course, the bolus dose required for sedation was determined and corresponded to the current dose of continuous infusion (for example, 100 micrograms IV push bolus fentanyl for a patient with a continuous infusion of 100 micrograms fentanyl per hour, if necessary) as long the NRS is less than 3 and the BPS, BPS-NI less than 5, or the pain score decreases by at least 3 points, or the pain is acceptable to the patient. Analgesics in the protocol mainly included Apotel, Ketorolac, and Fentanyl, Hydromorphone, Morphine, Remifentanyl and sedatives including Propofol, Dexmethomidine, Midazolam, and Lorazepam. Depending on the assessment of pain and restlessness and depending on which group the patient belongs to in terms of sedation (light, heavy, and normal), the dose of these drugs was increased or decreased. The starting time and dose of analgesic and sedative drug were recorded and monitored

Category

Treatment - Drugs

2

Description

Control group: In the control group, the routine method of pain assessment was not performed comprehensively and regularly. Usually the categorical scale was used to assess the pain and the patients themselves expressed the pain (conscious, without connecting to a ventilator) and to determine the level of restlessness, no tool was used to measure delirium and restlessness. Routine sedatives and analgesics were prescribed in the ward by the doctor and anesthetist if necessary. These included opioids (30 mg injectable pethidine TDS or PRN, 5 mg morphine PRN and 5 mg methadone BID, 5 mg midazolam PRN, as well as for patients connected to a ventilator, infusion of 1 to 2 mg midazolam and morphine

per hour was done) used for sedation and pain management. In the routine method, the nurse did not play an active role in deciding to prescribe analgesic-sedative drugs, and the medication was prescribed solely by the physician. In the control group, routine non-pharmacological care of the nurse, such as moving, maintaining a comfortable position and reducing ambient light at night, was performed to manage pain and restlessness.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

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Full name of responsible person

مریم هاشمی

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Sponsors / Funding sources

1

Sponsor

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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

Lorestan University of Medical Sciences

Proportion provided by this source

1

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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