Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 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

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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.
Age
From **18 years** old to **89 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target 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
Lorestan
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, Remifentanil 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

Name of organization / entity
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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
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
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Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
Nursery

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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