Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

The effect of person-centered care on the triage accuracy, pain control and patient experience of trauma patients in the emergency department: a randomized controlled trial(RCT)

Protocol summary

Study aim

Determining the effect of person-centered care on triage accuracy, patient experience and pain control in trauma patients

Design

The intervention group is triaged as soon as they enter the triage unit with a special triage scale (adjusted score of emergency medicine). Patient pain is assessed using the NRS scale and pain management is performed according to the pain management protocol. The third component will be performed simultaneously and in parallel with triage and pain management for the patient. In this group, the routine care method of the emergency department is generally performed.

Settings and conduct

Trauma patients in the emergency department of Shohada-e-Ashayer Hospital are randomly divided into intervention and control groups. Classes are made based on age and gender. We have 6 combinations of 4 blocks and they are selected randomly by placing blocks. Blindness does not apply in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria for patients include: Age 60-18 years. Abdominal, chest and orthopedic (musculoskeletal) traumas. Triage level 4-3 according to the triage system of emergency intensity index Exclusion criteria: Mental illness or cognitive impairment. Unstable hemodynamic status. Substance abuse and alcohol.

Intervention groups

The intervention group is triaged as soon as they enter the triage unit with a special triage scale (adjusted score of emergency medicine). Patient pain is assessed using the NRS scale and pain management is performed according to the pain management protocol. The third component will be performed simultaneously and in parallel with triage and pain management for the patient. In this group, the routine care method of the emergency department is generally performed.

Main outcome variables

accuracy of triage Satisfaction with pain control Intensity of pain Patients' experiences

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150919024080N20**
Registration date: **2021-10-26, 1400/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-26, 1400/08/04**
Update count: **0**

Registration date

2021-10-26, 1400/08/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of person-centered care on the triage accuracy, pain control and patient experience of trauma patients in the emergency department: a randomized controlled trial(RCT)

Public title
The effect of person-centered care on the triage accuracy, pain control and patient experience of trauma patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
(age 18-60 years) Abdominal, chest and orthopedic trauma (musculoskeletal) Having triage level 3 or 4 according to the ESI triage system Having acute pain means that the pain started 6 hours ago Having a minimum score of mild pain based on NRS having the ability to communicate The patient is alert and aware Injury Severity Score (ISS) in terms of anatomical area in the mild to moderate range No history of admission to the emergency room for 6 months Absence of sleeping pills, herbal medicines and other complementary medicine treatments from one month ago All injured transported by 115 emergency
Exclusion criteria:
Mental illness or cognitive impairment Unstable hemodynamic status Drug and alcohol abuse Serious diseases such as advanced liver disease, acute infectious diseases and chronic pain syndrome Active bleeding Transfer to the ICU or operating room Traumas of the face, head and neck and spinal cord Pregnancy Allergy to analgesics used in the present study Being treated with other pain and restlessness management protocols Participate in other emergency service enhancement interventions affecting experience Being admitted in an emergency department for less than 90 minutes Unwillingness to participate in the study
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
According to the inclusion and exclusion criteria, people enter the study in an accessible way. In order to equalize the distribution of two important confounders of age and sex, a class based on these two variables is created as age group 18 to 45 years / age group 46 to 65 years and men / women and then by Random blocks are placed in balance between intervention and control groups. The size of each block is 4 items, so that 6 different combinations of 4 blocks are created and are selected randomly by placing the blocks.
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
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
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Approval date
2021-08-10, 1400/05/19
Ethics committee reference number
IR.LUMS.REC.1400.105

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
Triage score: It is measured according to the specialized triage criteria of trauma patients.
Timepoint
Patients' triage score is measured at the time of

admission to the emergency room.

Method of measurement

Using the specialized triage criteria of mREMS trauma patients

2

Description

Pain intensity: Measured using the NRS criterion

Timepoint

Pain intensity is assessed upon arrival, 15, 30, and 60 minutes after analgesia according to the pain control protocol

Method of measurement

Using the NRS criterion

Secondary outcomes

1

Description

Triage accuracy: comes from the degree of agreement between the scorers, which includes the principal investigator and the emergency physician

Timepoint

Upon arrival of patients to the emergency room

Method of measurement

comes from the degree of agreement between the scorers, which includes the principal investigator and the emergency physician

2

Description

Pain control and management

Timepoint

At the onset and at 15, 30 and 60 minutes after the implementation of the pain control protocol

Method of measurement

It is measured in patients using the NRS system

3

Description

Satisfaction with pain control

Timepoint

When leaving the emergency department

Method of measurement

Using a questionnaire to assess patient satisfaction with pain control

4

Description

Patients' experiences

Timepoint

When leaving the emergency department

Method of measurement

Using the AEDQ questionnaire

Intervention groups

1

Description

Intervention group:Intervention The intervention in the present study will include a person-centered care package focusing on three components: a) specialized triage, b: pain management, c: communication therapy / conscious trauma care. Considering that the triage unit is the first service center for trauma victims, first the intervention group, as soon as it is accepted and enters the triage unit, by the main researcher (nurse trained in the field of triage) with a special triage scale that fits the needs, priorities and The condition of trauma patients is triage. This scale is the "Adjusted Emergency Medicine Score (mREMS)"The variables used in this scale include: patient age, systolic blood pressure, heart rate, respiration rate, blood oxygen saturation level and level of consciousness. The sum of the scores of these parameters determines the level of triage of patients. The degree of agreement between the scorers (reliability between the evaluators) is used to perform triage (nurse and emergency physician) to determine the accuracy of triage and the nurse and emergency physician simultaneously triage the patient according to the new criteria and the opinion of the specialist Emergency medicine is the standard gold.After determining the level of triage, pain management begins with a person-centered approach. In this way, the patient's pain is first assessed using the Numerical Pain Rating Scale (NRS), then if the patient needs pain medication based on a pain management protocol previously designed by the current research director and implemented in a previous study. Is . Patient pain management is done with the prescription of a nurse. In this protocol, the nurse is allowed to prescribe analgesics to the patient independently without first examining the patient by a physician.Paracetamol is the first treatment of choice and may be given non-steroidal anti-inflammatory drugs (NSAIDs) such as ketorolac and injectable or morphine suppositories if needed. Depending on the study approach, other options for analgesics such as fentanyl may be considered. Also, according to this protocol, the nurse is obliged to record and evaluate the pain during analgesic administration and re-examine it at intervals of 15 minutes, 30 minutes and one hour after analgesic administration. Allergies, medications, and vital signs, as well as pain assessment, are performed by a triage nurse using the NRS tool, which is color-coded on A4 paper.After determining the pain score, and according to the pain management protocol, for the injured, analgesics are prescribed by the nurse according to the algorithm. After prescribing the drugs based on the method of administration and the amount of pain, the patient's pain is re-examined by the nurse and in case of no pain relief (pain score greater than 4) or side effects and drug reactions due to analgesics, the appropriate decision to re-prescribe anti-pain drug Pain or cessation is taken in consultation with an emergency medicine specialist. For patients with known allergies to analgesics, consult a physician for alternative medicine. Oral analgesics are prescribed with the expectation that the patient will not vomit and will be able to tolerate oral medications orally.In order to provide person-centered

care, the third component of the current intervention will be a combination of patient-centered communication and conscious trauma care, which will be performed simultaneously and in parallel with triage and pain management in order to provide a supportive environment for the patient. To achieve this goal, during triage or pain management, the nurse has a dynamic, direct, and continuous presence at the patient's bedside and asks the patient to briefly describe their life situation (such as stress, social life, social support), and possible related experiences. Describe the diagnosis and treatment and previous experience related to hospitalization and pain management.If necessary, other risk factors related to trauma (such as drug use, alcohol use, mental health, etc.) are discussed. During the patient's admission to the emergency room, the patient and the nurse share information about the patient's management of pain, treatment plan and diagnosis, such as blood tests, examinations, imaging, and the use of analgesics, by reviewing the medical record. The nurse also acknowledges symptoms such as pain and fatigue and encourages the patient to describe the problems and barriers associated with managing their pain, and the treatment strategies, benefits, and risks of these treatments will be recommended and discussed.In this exchange of information and participation, factors such as pain, bruising and even emotional stress that are identified in patients' narratives are considered very important for managing emergency care problems and are planned for them. In this supportive context, the patient's participation in planning is emphasized so that the treatment process tailored to each individual's condition is discussed as part of the health care program.This intervention is a flexible intervention, but in the current study, based on the framework of this study, we pursue the same goals such as: patient satisfaction, patient respect, patient pain control, patient participation in the treatment program for all participants.

Category

Treatment - Other

2

Description

Control group : In this group, the routine care method of the emergency department is generally performed. In this study, the research environment is the same for the intervention and control groups. Triage of patients in the research environment is with the ESI system. The ESI system is a 5-level triage system that divides patients based on the severity of the disease and the facilities needed by the patient in the emergency room.No special tools are used to assess patients' pain and according to the patients themselves, pain assessment is performed and analgesics are prescribed according to the routine ward by the treating physician and emergency medicine if necessary and the nurse plays an active role in deciding to prescribe anti-pain drugs. There is no pain. Also, the patient-centered communication structure is not implemented in this group, and at the end, patients' experiences will be examined with a questionnaire for the intervention group.Before and during the study, nurses did not use any other standard pain management protocol and there was no structured measurement and recording of pain by nurses. In order to prevent contamination of the samples, we ask the patients in the intervention group to avoid sharing their experiences with other patients during the intervention, and try to keep the intervention and control groups in separate units.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Khoram-Abad University of Medical Sciences
Proportion provided by this source
10
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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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