Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effectiveness of Bupivacaine administration through chest tube and intercostal blockage on the narcotic dosage to control the pain induce by chest tube in the trauma patients

Protocol summary

Study aim

Comparison of the efficacy of pain relief in bupivacaine injection through chest tube and intercostal blockage on improvement of ABG indices, pain and need for intravenous analgesic in traumatic patients with rib fracture

Design

A clinical trial without the control group, with the parallel groups, no blinding, randomized

Settings and conduct

This not blind, randomized clinical trial will be performed at Kashani and Al-zahra hospitals in Isfahan. In this study 32 traumatic patients with rib fracture will be enrolled and randomly divided into two parallel groups. Then the blood factors including heart rate, HCO3, PO2, PCO2 of patients are recorded before the intervention and every 0.5 hours to 4 hours after the intervention. Pain scores were recorded before the intervention and every 10 minutes to 4 hours after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: trauma patients with rib fractures, abnormalities in ABG, consent to participate in the study, the presence of pentothorax and hemothorax. Exclusion criteria: need for intubation, sensitivity to bupivacaine, unstable conditions, need for further action, drug abuse, blood pressure less than 90/60 mmHg or greater than 180/110 mmHg.

Intervention groups

Intervention group 1: patients undergo intercostal blockage by the standard method with bupivacaine 0.5% as 0.1 ml/kg body weight. Intervention group 2: patients receive chest tube and 20 ml of bupivacaine 0.5% via chest tube Into the pleural space. All patients are given a single dose of the drug. Patients are monitored for up to 12 hours for the severity of pain and the need for opioids.

Main outcome variables

Narcotic dosage; Pain score; Bicarbonate (HCO3); pH; Pressure of O2 (PO2); Pressure of CO2 (PCO2)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120716010297N6**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-29, 1399/01/10**
Update count: **0**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name
Leili Allahbakhshian
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 1668 7079
Email address
allahbakhshian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of Bupivacaine administration through chest tube and intercostal blockage on the narcotic dosage to control the pain induce by chest tube in the trauma patients

Public title
The effectiveness of Bupivacaine administration to control the pain of chest tube
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Traumatic patients with rib fractures ABG3 abnormality Consent to participate in the study If there is pentothorax and hemothorax for the patient.
Exclusion criteria:
The patient is drug addicted The patient's blood pressure is less than 90/60 mmHg or greater than 180/110 mmHg that may cause the patient to require any further intervention The patient has unstable conditions and needs further action Need for intubation in patients Being allergic to bupivacaine
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were coded and randomly divided into two groups using random allocation software.
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
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jerib street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-02-12, 1398/11/23
Ethics committee reference number
IR.MUI.MED.REC.1398.585

Health conditions studied

1

Description of health condition studied
Rib fractures
ICD-10 code
S22.4
ICD-10 code description
Multiple fractures of ribs

Primary outcomes

1

Description
The amount of prescribed opioid analgesic medication
Timepoint
During the intervention
Method of measurement
Patient's records

2

Description
HCO3
Timepoint
Before the intervention and every 0.5 hours to 4 hours after the intervention
Method of measurement
blood test

3

Description
PO2
Timepoint
Before the intervention and every 0.5 hours to 4 hours after the intervention
Method of measurement
blood test

4

Description
PCO2

Timepoint
Before the intervention and every 0.5 hours to 4 hours after the intervention
Method of measurement
blood test

5

Description
Pain
Timepoint
Before the intervention and every 10 minutes to 4 hours after the intervention
Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In the first group, patients were subjected to intermittent blockage by standard method with bupivacaine 0.5% as 0.1 ml/kg body weight.
Category
Treatment - Drugs

2

Description
Intervention group 2: In the second group, the patient is implanted with a chest tube, and 20 ml of bupivacaine 0.5% is imported through the chest tube into the pleural space.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Mohammad NasrIsfahani
Street address
Ayatollah Kashani Hospital, Ayatollah Kashani Main Street
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
Phone
+98 31 3233 0091
Fax
Email
m_nasr@med.mui.ac.ir

2

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Mohammad Nasr Isfahani
Street address
Sofeh boulevard
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
Phone
+98 31 3620 2020
Email
m_nasr@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Nasr Isfahani
Street address
Department of Emergency Medicine; Alzahra Hospital; Sofeh boulevard
City
Iran
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
Phone
+98 31 3620 2020
Email
m_nasr@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Nasr Isfahani
Position
Assistant Professor of Emergency Medicine
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Department of Emergency Medicine; Alzahra Hospital; Sofeh boulevard
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3620 2020
Email
m_nasr@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Nasr Isfahani
Position
Assistant Professor of Emergency Medicine
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Alzahra Hospital; Sofeh boulevard
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3620 2020
Email
m_nasr@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Nasr Isfahani
Position
Assistant Professor of Emergency Medicine
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Department of Emergency Medicine; Alzahra Hospital; Sofeh boulevard
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3620 2020
Email
m_nasr@med.mui.ac.ir

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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available