Comparing the effectiveness of Bupivacaine administration through chest tube and intercostal blockage on the narcotic dosage to control the pain induced 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
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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 Nasr Isfahani
Street address
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2
Recruitment center
Name of recruitment center
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Full name of responsible person
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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
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
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
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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available