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

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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
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

The effectiveness of Bupivacaine administration to control the pain of chest tube

Traumatic patients with rib fractures ABG3 abnormality Consent to participate in the study If there is pentoctxox and hemothorax for the patient.

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

No age limit

Both

2

Patients were coded and randomly divided into two groups using random allocation software.

Not blinded

Placebo

Not used

Parallel

Secondary IDs
empty

Ethics committees

Ethics committee
Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Isfahan University of Medical Sciences, Hezar Jerib street

Isfahan

Isfehan

8174673461

2020-02-12, 1398/11/23

IR.MUI.MED.REC.1398.585

Health conditions studied

1

Rib fractures

S22.4

Multiple fractures of ribs

Primary outcomes

1

The amount of prescribed opioid analgesic medication

During the intervention

Patient’s records

2

HCO3

Before the intervention and every 0.5 hours to 4 hours after the intervention

blood test

3

PO2

Before the intervention and every 0.5 hours to 4 hours after the intervention

blood test

4

PCO2
Timepoint
Before the intervention and every 0.5 hours to 4 hours after the intervention

Method of measurement
blood test

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
Ayatollah Kashani Hospital, Ayatollah Kashani Main Street

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2
Recruitment center
Name of recruitment center
Al-Zahra Hospital

Full name of responsible person
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Esfahan University of Medical Sciences

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?
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
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- **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