

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Isfahan

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

Isfahan

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

Isfahan

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

Isfahan

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

8174673461

Person responsible for general inquiries

Phone

+98 31 3620 2020

Email

m_nasr@med.mui.ac.ir

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

Isfahan

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

Isfahan

Postal code

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

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City

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Province

Isfahan

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