

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing thoracic epidural infusion of Bupivacain versus Bupivacain plus dexmedetomidine in pain control of patients with multiple ribs fractures.

Protocol summary

Summary

In this randomized clinical trial, with purpose of Comparing thoracic epidural infusion of Bupivacain versus Bupivacain plus dexmedetomidine in pain control of patients with multiple ribs fractures, 64 trauma patients aged over 18 years old suffering from multiple (2 or more) unilateral rib fractures will be allocated to either pain control groups. This study will be conducted in Imam Reza medical center. Considering the inclusion and exclusion criteria, trauma patients admitted to the emergency department and suffering from multiple unilateral rib fractures will be allocated to either of the study groups. First group will receive continuous bupivacaine and dexmedetomidine through thoracic epidural catheter; whereas the second group will receive single continuous bupivacaine through thoracic epidural catheter for the first 24 hours from the admission. All patients for pain control four days measured by special table will control pain and analgesic effects of each group will collect and compare.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701299948N2**
Registration date: **2017-02-24, 1395/12/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-24, 1395/12/06

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing thoracic epidural infusion of Bupivacain versus Bupivacain plus dexmedetomidine in pain control of patients with multiple ribs fractures.

Public title

Pain control of ribs fractures.

Purpose

Treatment

Inclusion/Exclusion criteria

Including criteria: Traumatic patient with multiple ribs fracture greater than 2 ribs; Age after 18 y; Breathing sign due to trauma; G.C.S ≥ 14 Exclusion criteria: Chest wall trauma having brain or cervical vertebral trauma; Patient with hemostasis disorder; Sensitivity to

anesthetic drug; Patient without satisfaction; Systemic sepsis and local infection; Patient under mechanical ventilation; Patient with abdominal trauma; Patient without cooperation; Bilateral ribs fracture; Past history of psychological and nervous system disease and chronic analgesic users.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tabriz University of Medical Sciences

Street address

Tabriz daneshgah av., Tabriz University of Medical Sciences. anesthesiology department

City

tabriz

Postal code

۱۴۷۶۶-۰۱۶۶۶

Approval date

2017-01-09, 1395/10/20

Ethics committee reference number

IR.TBZMED.REC.1395.1111

Health conditions studied

1

Description of health condition studied

Chest pain, unspecified

ICD-10 code

S22.4

ICD-10 code description

Multiple fractures of ribs

Primary outcomes

1

Description

PAIN

Timepoint

Daily for four days.

Method of measurement

by visual analogue scale

Secondary outcomes

1

Description

multiple ribs fracture, pneumothorax, arterial blood gas level

Timepoint

daily for 4 days

Method of measurement

acordding to reported statistics

2

Description

Bleeding & hematoma

Timepoint

Daily for 4 days

Method of measurement

Based on clinical symptoms and visit of peocedure site

3

Description

Pneumothorax

Timepoint

Daily for 4 days

Method of measurement

Based on clinical symptoms and C.X.Ray if suspected

Intervention groups

1

Description

blocking and catheter placement in mid portion of previously pointed ribs fracture were done .then from the same pointed site local anesthetic solution(Bupivacain 0.25%, 1.5 cc per segment per fracture site after dosage test were injected. then catheter was ind-welled and (bupivacain 0.125%, 1ml/kg/hr infusion + dexmedetomidine 1 micro gram/kg bolus) was begin. each group was test for A.B.G for 4 days and oxygenation parameters is recorded.

Category

Treatment - Drugs

2

Description

In second group of patient thoracic epidural such the

other group was done. then after primary bolus dose was injected (bupivacain 0.25% , 1.5 ml per ribs fracture segments bolus then bupivacain 0.125%, 1 ml/kg/hr was infused).

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz Imam Reza Hospital

Full name of responsible person

Maryam Hoseini

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name

صفر

Grant code / Reference number

ندارد

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty