

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

comparison between thoracic epidural and intercostal block in pain management of patients with 3-4 traumatic rib fracture

Protocol summary

Study aim

Pain due to multiple (3-4) rib fractures of trauma patients compared between the thoracic epidural block and intercostal block.

Design

Clinical trial without a control group, with parallel groups, double-blind, performed on 86 patients.

Settings and conduct

The study is a randomized double-blind clinical trial in which patients with 3-4 rib fractures who are referred to Valiasr hospital in Arak who do not have pneumothorax and hemothorax are randomly divided into two groups. The thoracic epidural or intercostal block is performed by an anesthesiologist and then the intern in charge of the project, who is unaware of the grouping, will record the patients' information including pain score, hemodynamics, etc. in the questionnaire. Also, the statistician of the project consultant, who is not aware of the groups and only analyzes the two groups A and B.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with 3-4 rib fractures, age between 15 to 50 years, no underlying heart and lung disease, no hemothorax or pneumothorax, no pulmonary contusion, no sensitivity to marcaine and lidocaine, no drug allergy Exclusion criteria: patient's unwillingness to participate in the plan, contraindication for epidural or intercostal block, History of drug addiction

Intervention groups

Group A: patients with the thoracic epidural block. Group B: patients with the intercostal block.

Main outcome variables

Pain by score, mean of drug use, mean heart rate,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161017030336N8**

Registration date: **2021-11-23, 1400/09/02**

Registration timing: **retrospective**

Last update: **2022-08-03, 1401/05/12**

Update count: **1**

Registration date

2021-11-23, 1400/09/02

Registrant information

Name

Ghasem Habibi

Name of organization / entity

Islamic azad university

Country

Iran (Islamic Republic of)

Phone

+98 86 3367 3208

Email address

dr.habibi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-04, 1400/02/14

Expected recruitment end date

2021-09-05, 1400/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison between thoracic epidural and intercostal block in pain management of patients with 3-4 traumatic rib fracture

Public title

comparison between thoracic epidural and intercostal block in pain management of patients with 3-4 traumatic rib fracture

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with 3-4 rib fractures Age between 15 to 50 years Lack of underlying heart and lung disease Absence of hemothorax and pneumothorax Absence of pulmonary contusion Lack of sensitivity to marcaine and lidocaine Lack of sensitivity to drugs

Exclusion criteria:

The patient's unwillingness to participate in the plan History of drug addiction

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Thoracic trapezius or intercostal block is performed by the anesthesiologist in charge of the project and then the intern in charge of the project who is unaware of the grouping, patient information including pain score, hemodynamics, etc. will be recorded in the questionnaire. Also, the project consultant statistician who is in charge of data analysis is not aware of the groups and only analyzes the two groups A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Basij St., Campus of Arak University of Medical

Sciences

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2021-05-03, 1400/02/13

Ethics committee reference number

IR.ARAKMU.REC.1400.002

Health conditions studied

1

Description of health condition studied

Fracture of thoracic vertebra

ICD-10 code

S22.0

ICD-10 code description

Fracture of thoracic vertebra

2

Description of health condition studied

Multiple fractures of ribs

ICD-10 code

S22.4

ICD-10 code description

Multiple fractures of ribs

Primary outcomes

1

Description

Pain

Timepoint

In 15 minutes, one hour, 2 hours, 4 hours, 12 hours, 24 hours

Method of measurement

Visual Analogue Scale. In this scale, the number zero is considered painless and the number 10 is considered the maximum amount of pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients with thoracic epidural block are placed in a sitting position after taking a vein and giving 3 cc per kg of normal saline, and after washing the area using an epidural needle 20 in the thoracic space, depending on the fracture of the ribs, we will block the patient. The desired dose for the patient using marcaine is 0.25 to 0.3 cc per kg.

Category

Treatment - Other

2**Description**

Intervention group 2: Patients in the intercostal block group, after taking a vein and giving 3 cc / kg of normal saline while sitting or lying on their side, then the target area is washed and the intercostal block is prepared. Using a G22 needle and according to the fracture site, nerve block is performed through the intercostal space in the posterior region. The desired dose for inter-gear block is 0.2 cc / kg of marcaine 0.25.

Category

Treatment - Other

Recruitment centers1**Recruitment center****Name of recruitment center**

Vali Asr hospital, Arak

Full name of responsible person

Dr. Siamak Rakei Isfahani

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Pardis of Arak University of Medical Sciences,
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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Ali Karbasfroshan

Position

General Medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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

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Full name of responsible person

Dr. Siamak Rakei Isfahani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

There are no conditions for access to information.

From where data/document is obtainable

Vice Chancellor for Research, Arak University of Medical Sciences.+98 86 3417 3505

What processes are involved for a request to access data/document

The applicant can access the documents immediately after contacting the Vice Chancellor for Research of Arak University of Medical Sciences.

Comments