Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of periosteal block vs. intravenous morphine on reducing the pain of patients with distal radius and ulnar fracture

Protocol summary

Study aim
Pain control in patients with closed distal forearm fractures

Design
Two arm parallel group randomized trial with blinded intervention and outcome assessment

Settings and conduct
This study will be carried out at the emergency department of Sina Hospital, Tehran, Iran. The study is double blind. Patients, the person who will perform the procedure, as well as the person who measures the severity of pain, will be unaware of the groups.

Participants/Inclusion and exclusion criteria
Patients over the age of 18-year-old suffer from closed distal forearm fracture and class 1 or 2 according to the classification of American Society of Anesthesiologists are included. If there is any evidence of concurrent head trauma, multiple trauma, open fracture, compartment syndrome, or any contraindication or drug allergy to morphine or lidocaine are excluded.

Intervention groups
Intervention group: Priosteal block with lidocaine + intravenous placebo Control group: Local injection of placebo + intravenous morphine

Main outcome variables
In this study, visual analog scale will be used to measure pain intensity. In this way, this criterion will be recorded in both groups before injection and at 0, 15, 30, 45, and 60 minutes, and 75.90 after intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131203015640N6**
Registration date: **2018-02-20, 1396/12/01**
Registration timing: **registered_while_recruiting**
Last update: **2018-02-20, 1396/12/01**
Update count: **0**

Registration date
2018-02-20, 1396/12/01

Registrant information

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Alireza Baratloo

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-15, 1396/11/26

Expected recruitment end date
2019-01-20, 1397/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of periosteal block vs. intravenous morphine on reducing the pain of patients with distal radius and ulnar fracture

Public title
Periosteal block vs. intravenous morphine on reducing the pain of patients with distal forearm fracture

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Closed distal radius and/or ulnar fracture American Society of Anesthesiologists (ASA) class 1, 2

Exclusion criteria:

Open fractures Neurovascular compromise Multiple trauma Head Trauma Suspicion for compartment syndrome Allergy or contraindication for lidocaine or morphine administration

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

After entering the study, the patients are randomly divided into two groups and one group received intravenous morphine and local injection of placebo and the other group intravenous placebo and periosteal block. The procedure is carried out by a person who is unaware of the type of drugs and the assessment of pain is done by another person, who is also unaware of the groups.

Placebo

Used

Assignment

Parallel

Other design features

None

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Building no 1, School of medicine, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2017-07-12, 1396/04/21

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2838

Health conditions studied

1

Description of health condition studied

Patients with closed distal forearm fracture

ICD-10 code

S52.6

ICD-10 code description

Fracture of lower end of both ulna and radius

Primary outcomes

1

Description

Pain score

Timepoint

Minutes 0, 15, 30, 45, 60, 75 and 90 after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To perform the periosteal block, using a 10cc syringe containing lidocaine 1% at a distance of 6-8 cm proximal to the wrist of the lateral of the radius bone and medial of the ulnar bone are injected. In this group, distilled water will be injected intravenously as placebo.

Category

Treatment - Drugs

2

Description

Control group: Morphine sulfate with a dose of 0.1 mg/kg body weight and diluted in pre-prepared syringes with distilled water, so that each cc contains 1 mg of morphine. This amount will be infused slowly through the peripheral vein within 5 minutes. Block operations will also be performed using distilled water.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Ali Abdolrazaghnejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Ali Abdolrazaghnejad

Position
Assistant Professor

Latest degree
Medical doctor

Other areas of specialty/work
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
There is no further information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
No - There is not a plan to make this available
Title and more details about the data/document
Base information of the participants in the study, information on the main outcome and possible side effects
When the data will become available and for how long
starting Instantly after publication
To whom data/document is available
only available for people working in academic institutions
Under which criteria data/document could be used
Any analysis is allowed
From where data/document is obtainable
Contact with ali.abdorazzagh@gmail.com
What processes are involved for a request to access data/document
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Comments