

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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: Periosteal 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

Name

Alireza Baratloo

Name of organization / entity

Tehran University of Medical Sciences

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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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Imam Khomeini Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammadali Sahraian

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Deputy of research and technology, Tehran University of Medical Sciences, Keshavarz Bulvar

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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

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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

Contact with ali.abdorazzagh@gmail.com

Comments