

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of the success rate of hematoma block with and without ultrasound-guide in pain control of distal radial fracture reduction in patients presenting to the emergency department

Protocol summary

Summary

After obtaining ethics committee's approval for patients with distal radial fracture to Imam Reza hospital, based on inclusion criteria and obtaining informed consent were enrolled. Information including age, sex, drug history, previous and acute fracture is collected by a checklist. In this double blind clinical trial, 80 patients with acute fracture of distal radius from among ASA class 1 and 2 and older than 18 years select and were randomly divided into 2 groups: hematoma block without ultrasound guidance (A) and hematoma block with ultrasound guidance (B). In A group, after disinfection, lidocaine 1% is injected in the center of the hematoma and around ulnar styloid with Barbutazh technique. In B group at first we identify hematoma with ultrasound and then injection is done. Ten minutes after anesthesia block is proved by asking the patient and the pressure at the site of block then reduction is performed. Injection is done by research supervisor who is unaware about the method of choosing the site of injection. Pain during hematoma block and reduction is measured on the base of visual analogue scale. The method of evaluation is explained to the patient before and after injection. Patient satisfaction about analgesia is measured at the time of block and 30 minutes after according to the method as described method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020126315N1**

Registration date: **2016-06-04, 1395/03/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-04, 1395/03/15

Registrant information

Name

Assiyeh Baradaran fard

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the success rate of hematoma block with and without ultrasound-guide in pain control of distal radial fracture reduction in patients presenting to the emergency department

Public title

Evaluation of the success rate of hematoma block with and without ultrasound-guide in pain control of distal

radial fracture reduction in patients presenting to the emergency department

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Patients with acute fractures of the distal forearm ASA class I and II and among people over the age of 18 years Exclusion criteria: Older fractures than 12 hours; Open fractures due to technical problem; Patients with a history of drug abuse or any kind of debilitating CNS and respiratory medications

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: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, randomization is made with random numbers table in patients above 18 years with acute distal radius fracture.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Pardis of Ferdowsi University, Azadi square, Mashhad

City

Mashhad

Postal code

917794-8564

Approval date

2015-06-10, 1394/03/20

Ethics committee reference number

IR.MUMS.sm.REC.1394.132

Health conditions studied

1

Description of health condition studied

Fracture of the distal radius

ICD-10 code

S52.5

ICD-10 code description

Fracture of lower end of radius

Primary outcomes

1

Description

pain score

Timepoint

before block, 30 minutes after reduction

Method of measurement

visual analog scale

Secondary outcomes

1

Description

reducton time

Timepoint

reduction time

Method of measurement

minute

Intervention groups

1

Description

In A group, hematoma block without ultrasound guidance, after disinfection, lidocaine 1% is injected in the center of the hematoma and around ulnar styloid with Barbutazh technique. Ten minutes after anesthesia block is proved by asking the patient and the pressure at the site of block then reduction is performed. Injection and reduction are done by research supervisor. Pain during hematoma block and reduction, is measured on the base of visual analogue scale by research fellow who is unaware about the method of choosing the site of injection. The method of evaluation is explained to the patient before and after injection. Patient satisfaction about analgesia is measured at the time of block and 30 minutes after according to the method as described method.

Category

Diagnosis

2

Description

In B group, hematoma block with ultrasound guidance, at first we identify hematoma with ultrasound and after disinfection, lidocaine 1% is injected in the center of the hematoma and around ulnar styloid with Barbutazh technique. Ten minutes after anesthesia block is proved

by asking the patient and the pressure at the site of block then reduction is performed. Injection and reduction are done by research supervisor. Pain during hematoma block and reduction, is measured on the base of visual analogue scale by research fellow who is unaware about the method of choosing the site of injection. The method of evaluation is explained to the patient before and after injection. Patient satisfaction about analgesia is measured at the time of block and 30 minutes after according to the method as described method.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department of Imam Reza (AS) hospital

Full name of responsible person

Dr. Assiyeh Baradaran Fard

Street address

Edalatian emergency department, Imam Reza (AS) hospital, Ibn Sina street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences Vice chancellor for research

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Vice Chancellor for Research and Technology, Mashhad University of Medical Sciences, Daneshgah street

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences Vice chancellor for research

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Assiyeh Baradaran Fard

Position

Resident of emergency medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address**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