

# 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)

###### Phone

+98 51 3767 0588

###### Email address

baradaranfa921@mums.ac.ir

##### 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****Street address**

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**Full name of responsible person**

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**Position**

Assistant professor of emergency medicine

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**Full name of responsible person**

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**Position**

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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*