

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the Results of Single-Injection Nerve Block with the Traditional Method in Patients Requiring Digital Anesthesia

#### Protocol summary

##### Study aim

To investigate the results of single-injection nerve block for digital anesthesia

##### Design

Randomized controlled clinical trial

##### Settings and conduct

The study will be conducted in Shohada-ye Ashayer Teaching Hospital, in Khorramabd, Iran. Participants will be recruited from those who require hand surgery in the center and meet the inclusion criteria. As the surgeon and the patients will notice the difference between traditional injection and single injection technique, blinding is not possible.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients requiring hand surgery at Shohada-ye Ashayer Teaching Hospital in Khorramabad, age 18 years and older Exclusion criteria: Subjects with a history of previous surgery on the ipsilateral hand, subjects who discontinue their cooperation with the research team

##### Intervention groups

Intervention group: The single injection method will be performed by injecting 3 ml of 1% lidocaine at the base of the finger in the proximal volar metacarpophalangeal region. Control group: The traditional technique will be performed by injecting 1.5 ml of 1% lidocaine without epinephrine in each lateral part of the base of the finger, just distal to the metacarpophalangeal joint, at the level of the web spaces. In all cases, a 27 G needle will be used.

##### Main outcome variables

Change in the pain reported by the patient (pain measured by the Visual Analogue Scale)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230410057871N1**

Registration date: **2023-07-09, 1402/04/18**

Registration timing: **prospective**

Last update: **2023-07-09, 1402/04/18**

Update count: **0**

##### Registration date

2023-07-09, 1402/04/18

##### Registrant information

###### Name

Arian Karimi Rouzbahani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 66 3324 1229

###### Email address

arian.karimi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Results of Single-Injection Nerve Block with the Traditional Method in Patients Requiring Digital Anesthesia

##### Public title

Investigation of the Results of Single-injection Nerve Block

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All patients requiring hand surgery at Shohada-ye Ashayer Teaching Hospital in Khorramabad. Age 18 years and older

### Exclusion criteria:

Subjects with a history of previous surgery on the ipsilateral hand  
Subjects who discontinue their cooperation with the research team

## Age

From **18 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

Randomization will be performed using the Balanced Block Randomization method and the participants will be divided into single-injection or control (traditional injection) groups.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

### Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

##### Street address

Lorestan University of Medical Sciences, opposite Kahrizak village, km 5 of Khorramabad Road - Boroujerd, Khorramabad, Lorestan, Iran

##### City

Khorramabad

##### Province

Lorestan

##### Postal code

6814993165

## Approval date

2023-02-15, 1401/11/26

## Ethics committee reference number

IR.LUMS.REC.1401.303

## Health conditions studied

### 1

#### Description of health condition studied

Hand surgery

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Change in the pain reported by the patient (pain measured by the Visual Analogue Scale)

#### Timepoint

The pain level will be recorded patient at 1, 3, 5, 15, and 20 minutes.

#### Method of measurement

The patient's pain after the injection is measured with a ruler that ranges from 0 to 10 cm so that 0 is the sign of no pain and 10 is the most severe pain ever experienced.

## Secondary outcomes

### 1

#### Description

Analgesia onset time in patients in the two groups

#### Timepoint

Minutes 1, 3, 5, 15 and 20

#### Method of measurement

The level of pain will be recorded at 1, 3, 5, 15, and 20 minutes.

### 2

#### Description

The rate of complications caused by the treatment including arterial blood oxygen saturation below 90% for more than 60 seconds, change in pulse rate or blood pressure (increase or decrease), change in respiratory rate (increase or decrease), side effects (nausea and vomiting or loss of consciousness)

#### Timepoint

Minutes 1, 3, 5, 15 and 20

#### Method of measurement

Arterial blood oxygen saturation will be measured by a pulse oximeter from the first finger of the right or left hand. Any drop below 90% for more than 60 seconds will be considered positive. Its absolute amount will be recorded in the 5 defined times.

### 3

#### Description

Overall satisfaction of patients 60 minutes after the end

of receiving the medication

#### **Timepoint**

Minutes 1, 3, 5, 15 and 20

#### **Method of measurement**

Overall satisfaction will be evaluated based on a 5-point scale (0=poor, 1=moderate, 2=good, 3=very good, 4=excellent) within 60 minutes after receiving the medication.

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The single injection method will be performed by injecting 3 ml of 1% lidocaine at the base of the finger in the proximal volar metacarpophalangeal region. In all cases, a 27 G needle will be used.

#### **Category**

Treatment - Surgery

### **2**

#### **Description**

Control group: The traditional technique will be performed by injecting 1.5 ml of 1% lidocaine without epinephrine in each lateral part of the base of the finger, just distal to the metacarpophalangeal joint, at the level of the web spaces.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Shohada-ye Ashayer Teaching Hospital

##### **Full name of responsible person**

Mohammad Kazem Shahmoradi

##### **Street address**

Iran, Lorestan, Khorramabad, Enghelab St

##### **City**

Khorramabad

##### **Province**

Lorestan

##### **Postal code**

68169 33132

##### **Phone**

+98 66 3323 6401

##### **Email**

Shahmoradi.m@lums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Khoram-Abad University of Medical Sciences

##### **Full name of responsible person**

Bahram Rasoulia

#### **Street address**

Lorestan University of Medical Sciences, opposite Kahrizak village, km 5 of Khorramabad Road - Boroujerd, Khorramabad, Lorestan, Iran

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#### **Email**

rasoulia@lums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Khoram-Abad 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**

Khoram-Abad University of Medical Sciences

##### **Full name of responsible person**

Arian Karimi Rouzbahani

##### **Position**

Medical student

##### **Latest degree**

A Level or less

##### **Other areas of specialty/work**

General Surgery

##### **Street address**

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##### **Postal code**

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##### **Email**

arian.karimi@sbmu.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Mohammad Kazem Shahmoradi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Arian Karimi Rouzbahani

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Surgery

**Street address**

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arian.karimi@sbm.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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