

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)

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+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

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Postal code

68169 33132

Phone

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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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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

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Person responsible for scientific inquiries

Contact

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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

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Latest degree

A Level or less

Other areas of specialty/work

General Surgery

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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