

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of satisfaction, pain and other complication in proximal and distal ulnar nerve local anesthesia in patients undergoing angiography via palmar artery

Protocol summary

Study aim

Determination and comparison of satisfaction, pain and other complications in two methods of local anesthesia in distal and proximal ulnar nerve in patients undergoing trans-palmar coronary artery angiography

Design

This study is a single-blind randomized clinical trial with parallel randomized groups on 54 patients who are candidates for angiography referred to Shahid Chamran Heart Center, Isfahan University of Medical Sciences. simple randomization method and trial phase 2-3 was performed After selecting patients, satisfaction, pain and complications such as vascular spasm, paresthesia were evaluated

Settings and conduct

In Shahid Chamran Heart Center, local anesthetic injection was done in the distal and proximal ulnar nerve and a comparison of satisfactions, pain, and other complications was performed. Single blindness(analyzer) was performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- All patients who are candidates for angiography referred to Chamran Hospital Isfahan University of Medical Sciences 2- Patient consent to participate in this study Exclusion criteria: 1- Having Raynaud's syndrome 2. Having vascular disorders of the upper extremities 3. Carpal tunnel syndrome 4 - Having sensory-motor disorders that affect the ulnar and median nerves Given 5. Chronic tenosynovitis

Intervention groups

They are placed under local anesthesia by proximal method. In this method, 1% lidocaine is used as subcutaneous 3-5 ml It is located in the area 2 cm proximal to the internal ulnar epicondyle Salcus will be injected at a 45 degree angle. The control group will receive the anesthetic at the wrist (distal).

Main outcome variables

Selecting the appropriate anesthesia method in performing trans-palmar coronary angiography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181228042155N3**

Registration date: **2020-09-05, 1399/06/15**

Registration timing: **retrospective**

Last update: **2020-09-05, 1399/06/15**

Update count: **0**

Registration date

2020-09-05, 1399/06/15

Registrant information

Name

Mohammad Kermani-Alghoraishi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

2019-09-11, 1398/06/20

Actual recruitment end date

2020-07-22, 1399/05/01

Trial completion date

2020-08-22, 1399/06/01

Scientific title

Comparison of satisfaction, pain and other complication in proximal and distal ulnar nerve local anesthesia in patients undergoing angiography via palmar artery

Public title

Comparison of proximal and distal ulnar nerve local anesthesia in patients undergoing angiography via palmar artery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients candidate for trans palmar coronary angiography that admitted to Shahid Chamran hospital
Patient consent to participate in this study

Exclusion criteria:

Raynaud's syndrome
Upper extremity vascular disorders
Having sensory-motor disorders that affect the ulnar nerves
Chronic tenosynovitis
Existence of any arthritis or joint disease involving the elbow and proximal forearm

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyst

Sample size

Target sample size: **60**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method using a table of random numbers

Blinding (investigator's opinion)

Single blinded

Blinding description

Given that the patient and physician know the location of the anesthetic injection, blindness is only about collecting and analyzing data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jarib st

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-09-07, 1398/06/16

Ethics committee reference number

IR.MUI.MED.REC.1398.320

Health conditions studied

1

Description of health condition studied

Evaluation of appropriate anesthesia in coronary angiography through palmar artery

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes

1

Description

Pain

Timepoint

One hour, four hours, twelve hours and one month after the procedure

Method of measurement

Visual analogue scale

2

Description

Satisfaction

Timepoint

One hour, four hours, twelve hours and one month after the procedure

Method of measurement

Questionnaire

3

Description

Vascular spasm

Timepoint

One hour, four hours, twelve hours and one month after the procedure

Method of measurement

Clinical and clinical observation

4

Description

Ulnar nerve damage

Timepoint

One hour, four hours, twelve hours and one month after the procedure

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group; patients are placed under local proximal anesthesia. In this method, 1% lidocaine in the form of subcutaneous (3-5 ml) is used, which is injected in the proximal 2 cm area into the internal epicondyle and ulnarsalculus (at a 45 degree angle). Anesthesia is done with an insulin syringe

Category

Treatment - Other

2

Description

Control group:for Patients, local anesthesia was done at distal part of ulnar nerve

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid chamran hospital

Full name of responsible person

Fereshteh-Farazandeh

Street address

Salman farsi st,moshtagh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Farshad roghani

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roghani_eint@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Kermani-Alghoraishi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Unidentifiable data on the main outcome of the study will be provided to researchers upon individual or academic request

When the data will become available and for how long

Six months to one year after the publication of the article - according to the rules of the journal

To whom data/document is available

Academic and scientific researchers

Under which criteria data/document could be used

For use in similar studies to complete research

From where data/document is obtainable

corresponding authors email of published article Email of Dr Mohammad Kermani-Alghoraishi : sm.kermani@med.mui.ac.ir Email of Dr Farshad Roghani-Dehkordi : roghani_int@yahoo.com

What processes are involved for a request to access data/document

After the article was published, according to the rules of the journal, the applicant can request the documents by an email to the corresponding author. Response time is between 1 to 4 weeks depending on the type of request.

Comments