

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of injectable lidocaine with and without topical lidocaine P ointment on pain, spasm and vasovagal syndrome in patients undergoing radial artery angiography

Protocol summary

Study aim

Determining the effect of injectable lidocaine with and without topical lidocaine P ointment on pain, spasm and vasovagal syndrome in patients undergoing angiography through radial artery

Design

randomized controlled clinical trial on 80 patients, A randomized, single-blind. A random number table will be used for randomization.

Settings and conduct

It makes sense to use a non-injectable topical drug to achieve the desired anesthesia for the therapist. The aim of this study was to evaluate the effect of lidocaine injection with and without lidocaine p ointment on radial artery catheterization. Shahid Modarres Hospital, Tehran. Patients will be randomly divided into study and control groups. All patients will be unaware of the content of the ointment used.

Participants/Inclusion and exclusion criteria

Patients over 18 years Allen normal test No Raynaud's disease Satisfaction with the research exclusion criteria: History of ointment allergy, structural disorders such as wrist surgery, having a fistula in the hand, having a weak pulse, having a high INR

Intervention groups

Patients will be randomly divided into case groups (receiving lidocaine-Pi and subcutaneous injection of lidocaine) and control (subcutaneous injection of lidocaine without ointment).

Main outcome variables

Pain score; Incidence of spasm; Temperature; Incidence of the vasovagal syndrome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210829052318N1**

Registration date: **2022-05-24, 1401/03/03**

Registration timing: **retrospective**

Last update: **2022-05-24, 1401/03/03**

Update count: **0**

Registration date

2022-05-24, 1401/03/03

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2021-12-25, 1400/10/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of injectable lidocaine with and without topical lidocaine P ointment on pain, spasm and vasovagal

syndrome in patients undergoing radial artery angiography Public title The effect of lidocaine on pain, spasm and vasovagal syndrome Purpose Prevention Inclusion/Exclusion criteria Inclusion criteria: No Arthropathy in the upper extremities Allen normal test No Raynaud's disease No Q wave infarction in the past week No history of contrast agent allergy Satisfaction with the research people over 18 years old Exclusion criteria: History of allergies to this ointment History of structural disorders such as wrist surgery Having a weak pulse Having a high INR History of fistula in hand Age From 18 years old Gender Both Phase 3 Groups that have been masked Participant Sample size Target sample size: 80 Randomization (investigator's opinion) Randomized Randomization description Step 1: Create a random sequence. A simple random method in which randomization is based on a single sequence of random allocations. The method of randomization is a table of random numbers. The researcher first determines the table to read the numbers (for example, right), then the numbers will be considered for different groups (for example, even numbers for intervention A and odd numbers for intervention B), then the researcher on one It gives up numbers and moves in one of the predetermined directions and records the numbers and assigns them to different groups. Step 2: Hide the allocation: Use randomly coded boxes: In these boxes, the intervention or the sheets in which the random allocation is registered will be used. Step 3: Execute the random allocation process: In order to create a random sequence, the participants will be examined in terms of entry and exit criteria and their names will be registered and the participants will be assigned to groups separate from the researchers. Blinding (investigator's opinion) Single blinded Blinding description In the present study, all eligible patients will be unaware of the contents of the ointments used and applied and the effects of the ointment, and the ointment tube will be covered by a cover. Placebo Used Assignment	Parallel Other design features Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Shahid Beheshti University of Medical Sciences Street address District 7, Madani St., Shemirani Alley, No. 60, first floor City Tehran Province Tehran Postal code 1617745711 Approval date 2022-02-21, 1400/12/02 Ethics committee reference number IR.SBMU.RETECH.REC.1400.1048 Health conditions studied <u>1</u> Description of health condition studied Coronary angiography patients through radial artery ICD-10 code ICD-10 code description Primary outcomes <u>1</u> Description Pain score according to the patient's statement and based on VAS Timepoint During angiography Method of measurement Patient statement based on Visual analogue scale(VAS) Secondary outcomes empty Intervention groups <u>1</u> Description Intervention group: Treatment with topical cream (lidocaine / prilocaine) under the brand name Zila-P in patients undergoing angiography. Each 100 grams
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contains: 2.5 grams of lidocaine and 2.5 grams of prilocaine. Produced by Tehran Shimi Pharmaceutical Company. At a rate of 3 grams and put padded glue on it

Category

Treatment - Drugs

2**Description**

Control group: Patients who did not use any ointment.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Modarres Hospital, Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

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Full name of responsible person

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Position

Associate professor

Latest degree

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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