

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of local anesthesia with lidocaine spray on the pain control of patients under radial coronary angiography

Protocol summary

Study aim

Determining the effect of local anesthesia with lidocaine spray on pain control in patients undergoing radial coronary angiography

Design

A three-group clinical trial with a control group, with parallel groups, randomized with the participation of 228 patients. For randomization, permutation blocks of 6 will be used.

Settings and conduct

The present study will be conducted as a three-group clinical trial study with the participation of 228 patients who are candidates for coronary angiography in Bushehr City Heart Hospital in 2022. Patients will be randomly divided into three intervention and control groups using permutation blocks. In the control group, only injectable lidocaine will be used to anesthetize the needle entry area. In the first intervention group, in addition to injectable lidocaine, lidocaine spray will also be used. In the second intervention group, only lidocaine spray will be used to anesthetize the needle entry area.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ischemic heart disease confirmed by the attending physician, Performing radial angiography for the first time, Elective patients for angiography
Exclusion criteria: Sensitization to lidocaine skin spray, Lack of stability of vital signs during the procedure

Intervention groups

Intervention groups: The first intervention group (A) will receive 6 puffs of 10% lidocaine spray 5 minutes before the angiography from a distance of 5 cm around the inside of the wrist, and then they will receive injectable lidocaine and then proceed to angiography. The second intervention group (B) will receive 6 puffs of 10% lidocaine spray 5 minutes before the angiography from a distance of 5 cm from the inside of the wrist. On the contrary, the control group and the first test group will not receive injectable lidocaine.

Main outcome variables

Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N39**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-21, 1401/06/30

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of local anesthesia with lidocaine spray on the pain control of patients under radial coronary angiography

Public title

The effect of local anesthesia with lidocaine spray on the pain control

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Ischemic heart disease confirmed by the physician
Performing radial angiography for the first time
Elective patients for angiography

Exclusion criteria:

Lack of stability of vital signs before the procedure
Sensitization to lidocaine skin spray

Age

From **19 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **228**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected through available sampling based on the inclusion criteria. The samples will be randomly assigned to three groups (two intervention groups and one control group) using block randomization method such as AABBC, ACCBAB.

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 Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2022-06-11, 1401/03/21

Ethics committee reference number

IR.UMSHA.REC.1401.266

Health conditions studied

1

Description of health condition studied

Coronary heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Pain severity

Timepoint

Immediately after entering the needle and 30 minutes later

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group(A): The first intervention group (A) will receive 6 puffs of 10% lidocaine spray 5 minutes before the angiography from a distance of 5 cm around the inside of the wrist, and then they will receive injectable lidocaine and then proceed to angiography.

Category

N/A

2

Description

Intervention group (B): The second intervention group receives 6 puffs of 10% lidocaine spray 5 minutes before angiography from a distance of 5 cm from inside the wrist. On the contrary, the control group and the first experimental group do not receive injectable lidocaine.

Category

N/A

3

Description

Control group: The control group will receive the usual anesthetic procedures before angiography, which includes 0.6-1 cc of lidocaine injection of 2% in the area around the styloid bone, and then they will pierce the radial artery with a #20 needle and place a 6-French arterial sheath and they will perform vascular angiography.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Boushehr heart hospital

Full name of responsible person

Asghar Bahrani

Street address

Boushehr heart hospital, Imam Khomeini Street.

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokouhi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Sajad Ebrahimi

Position

Studentd

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Khodayar Oshvandi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position
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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