Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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 AABBCC, 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
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Boushehr heart hospital, Imam Khomeini Street.
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Sponsors / Funding sources

1

Sponsor
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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
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Sajad Ebrahimi
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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