Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of the combined topical gel containing diltiazem, papaverine and lidocaine on hand function, pain, radial artery spasm and sympathetic tone in patients undergoing Trans radial cardiac catheterization

Protocol summary

Study aim
Determining the effect of combined topical gel of diltiazem, papaverine and lidocaine on hand function, pain, radial artery spasm and sympathetic tone in patients undergoing radial cardiac catheterization.

Design
A clinical trial with a control group with a three-blind parallel group, randomized by block method, phase 3 of the trial on 48 patients who are candidates for PCI.

Settings and conduct
The Cath-Lab and CCU department will be in Imam Khomeini Hospital (RA) of Amol city. Patients will be divided into two groups of patients receiving the combined topical gel (A) and the placebo group (B) using a randomized block and triple-blind method. 30 to 60 minutes before the radial artery catheterization, a certain amount (fingertip) of the combined gel is applied in the right wrist area, the location of the radial artery pulse in the intervention group, and the same amount of placebo is applied in the control group. After the patients are admitted to the lab, catheterization is performed by the attending physician. Catheterization of all patients will be performed by the attending physician. Before, during and after radial artery catheterization, pain and sympathetic tone will be evaluated in two groups. Hand function will be evaluated before and two hours after catheter removal (after TR BAND removal). Occurrence of radial artery spasm is also checked during catheterization.

Participants/Inclusion and exclusion criteria
1. Patients with coronary heart disease and clinical candidates for radial catheterization for diagnostic or therapeutic intervention. 2. Able to understand Persian language 3. Providing written consent 4. Age over 18 years 5. Absence of pain and previous injury in the right hand

Intervention groups
Topical gel recipient

Main outcome variables
Radial artery spasm, hand function, pain, sympathetic tone

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231018059760N1**
Registration date: **2024-01-09, 1402/10/19**
Registration timing: **prospective**

Last update: **2024-01-09, 1402/10/19**
Update count: **0**

Registration date
2024-01-09, 1402/10/19

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-10, 1402/10/20

Expected recruitment end date
2024-03-18, 1402/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the combined topical gel containing diltiazem, papaverine and lidocaine on hand function, pain, radial artery spasm and sympathetic tone in patients undergoing Trans radial cardiac catheterization

Public title
The effect of the combined topical gel containing diltiazem, papaverine and lidocaine on hand function, pain, radial artery spasm and sympathetic tone in patients undergoing Trans radial cardiac catheterization
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with coronary heart disease and clinical candidates for radial catheterization for diagnostic or therapeutic interventions. Able to understand Persian language Providing written consent Age above 18 years No previous pain and injury in the right hand
Exclusion criteria:
Atrioventricular block QRS prolongation of more than 120 milliseconds Parkinson's disease Long QT intervals of more than 0.44 seconds breastfeeding pregnancy Known liver dysfunction Type D response in Barbeau test Acute coronary syndrome Raynaud's syndrome Known history of hypersensitivity to local anesthetics Radial pulse not palpable Systolic blood pressure drop of less than 90 mmHg More than two attempts to reach the radial artery Lack of radial artery access and femoral access as an alternative solution History of radial artery access in the last 6 months
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be placed in one of the two test groups (receiver of combined topical gel of diltiazem, papaverine and lidocaine) and control (placebo) by block randomization method. According to the 6 possible ways of placing letters in blocks of four, these blocks are numbered with numbers one to six. . (AABB1-ABBA2-BABA3-BBAA4-BABA5-ABAB6) Then, using Random Allocation Software 2.0, one of the numbers one to six will be randomly selected for 12 times. Each number will specify four placement modes in a block. Blocks of four will be placed in 12 non-transparent envelopes in numbered order according to the sequence of random selection and these envelopes will be sealed by someone outside the research team who is unaware of the research objectives and the allocation of people to the groups under study. . The envelopes will be opened in order and the patients will be assigned to the respective groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
It is in the form of three blinds. That is, both the participant and the researchers and the interventionist doctor and the nurse collecting the data will be blind to the placement of the patient in the intervention or placebo group. For this purpose, the drug and placebo will be prepared in same shape and without name labels tubes. These tubes are tagged A and B. Only the principal researcher will know which tube contains drug and which placebo. The patient, nurse and doctor of Cat.Lab. department, data collector and even the statistical analyzer will be unaware of the tubes contents. Patients will be randomly assigned to one of A or B groups in a block method.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Mazandaran University of Medical Sciences
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Moallem Sq
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Postal code
1111112
Approval date
2023-12-09, 1402/09/18
Ethics committee reference number
IR.MAZUMS.REC.1402.521

Health conditions studied

1

Description of health condition studied
Candidate patients for angiography and angioplasty through the radial artery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Radial artery spasm
Timepoint
During catheterization
Method of measurement
Using the radial artery spasm scoring scale

2

Description
hand function
Timepoint
before the start of catheterization and two hours after catheter removal
Method of measurement
Using the tool: HAKIR Questionnaire (HQ-8)

3

Description
the pain
Timepoint
Before, during and after catheterization
Method of measurement
using visual analog scale (VAS)

4

Description
Sympathetic tone
Timepoint
Before, during and after catheterization
Method of measurement
Using a hemodynamic monitoring device and a pulse oximeter

Secondary outcomes

1

Description
Number of attempts to access the radial artery
Timepoint
During catheterization
Method of measurement
It will be calculated as the number of passes of the needle through the skin and will be observed and recorded by the researcher

2

Description
Lack of access to the radial artery
Timepoint
During catheterization
Method of measurement
The sheath cannot be inserted or pressure is not detected.

Intervention groups

1

Description
Intervention group: recipient of combined topical gel
Category
Treatment - Drugs

2

Description
Control group: receiving placebo gel
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital (RA) Amol
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
IR.MAZUMS..REC.1402.18831

Grant code / Reference number

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

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
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Position
Nursing Graduate Student

Latest degree
Master

Other areas of specialty/work
Nursery

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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
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document

wwer

When the data will become available and for how long

redf

To whom data/document is available

rtgf

Under which criteria data/document could be used

trfg

From where data/document is obtainable

hgty

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

hujy

Comments