

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Name

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Name of organization / entity

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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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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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Full name of responsible person

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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
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Country of origin
Type of organization providing the funding
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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