

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the Efficacy of Combined Topical Gel of Verapamil, Nitroglycerin and Lidocain in Prevention of Radial Artery Spasm During Transradial Angioplasty

Protocol summary

Study aim

In this study, the efficacy of combined topical gel of verapamil, nitroglycerin and lidocaine will be investigated in preventing radial artery spasm during angioplasty via radial artery.

Design

Randomized, two-blinded, parallel, placebo-controlled clinical trial with 64 patients in each group.

Settings and conduct

This two blind study will be done in Tehran Heart Center. Health care providers and patients are blind. Patients fall into two groups using block randomization. One group received placebo gel and other received therapeutic gel. The basal diameter of radial artery is measured with ultrasound. 0.5 to 1 hour before process, the therapeutic or the placebo gel are applied on the radial artery pulse, and then covered with a transparent dressing. After removing the gel, the radial artery diameter is measured with ultrasound before process beginning. During PCI, following parameters is recorded: Sedative drug and its dose, Sheath insertion in one or more attempts, Wire passage in one or more attempts, Vasodilator parenteral cocktail used, Sympathetic system response, Radial artery spasm score, Patient forearm pain. After performing PCI, radial artery is reevaluated with ultrasound.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age older than 18 years old Radial elective PCI candidates
Exclusion criteria:
Hypersensitivity or contraindication to lidocaine
Hypersensitivity or contraindication to nitroglycerin
Baseline weak radial pulse
Inadequate blood supply to palm
Presence of arteriovenous fistula for dialysis
Pregnant women or nursing mothers

Intervention groups

Intervention group: Combined Topical Gel of Verapamil, Nitroglycerin and Lidocain will be applied before PCI.

Control group: Placebo gel will be applied before PCI.

Main outcome variables

Radial artery spasm: Change in Radial artery diameter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200128046296N1**

Registration date: **2020-03-21, 1399/01/02**

Registration timing: **prospective**

Last update: **2020-03-21, 1399/01/02**

Update count: **0**

Registration date

2020-03-21, 1399/01/02

Registrant information

Name

Sevda Mikaeili Mirak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3252 5056

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Efficacy of Combined Topical Gel of Verapamil, Nitroglycerin and Lidocain in Prevention of Radial Artery Spasm During Transradial Angioplasty

Public title

Evaluation of the Efficacy of Combined Topical Gel of Verapamil, Nitroglycerin and Lidocain in Prevention of Radial Artery Spasm Incidence

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 18 years or older Elective radial PCI candidates

Exclusion criteria:

Hypersensitivity or contraindication to lidocaine
Hypersensitivity or contraindication to nitroglycerin
Baseline weak radial pulse Inadequate blood supply to palm Presence of arteriovenous fistula for dialysis
Pregnant women or nursing mothers

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample sizeTarget sample size: **128****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization method of this study is permuted block randomization individually. The randomized list of numbers 1 to 128 is randomly divided into two groups A or B, and the admitted patients are listed in group A or B, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a two blind clinical trial conducted at Tehran Heart Center. Patients fall into two groups using block randomization. One group received placebo gel and other received therapeutic gel.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

0

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.TUMS.VCR.REC.1398.807

Health conditions studied**1****Description of health condition studied**

Chronic Coronary Syndrome

ICD-10 code

I20

ICD-10 code description

Angina pectoris

Primary outcomes**1****Description**

Radial artery diameter

Timepoint

Before gel application and just after

Method of measurement

Radial artery ultrasound

2**Description**

Radial artery spasm

Timepoint

During angioplasty

Method of measurement

Radial artery spasm score: A) Verbal or nonverbal expression of discomfort in the forearm during catheter/sheath manipulation: Absent: 0; Present: 1; B) Difficulty in manipulating the catheter: Absent: 0; Present: 1; C) Difficulty in sheath removal: Absent: 0; Present: 1; D) Additional use of intraarterial nitroglycerine or verapamil after the initial vasodilator cocktail for suspected radial artery spasm: No: 0; Yes: 1. Incidence of radial artery spasm indicated by a Radial artery spasm score of 1 or more.

3

Description

Patient pain

Timepoint

After sheath insertion during angioplasty

Method of measurement

Visual analoug scale and verbal scale of pain

4

Description

Sympathetic system response

Timepoint

Before angioplasty and then after

Method of measurement

Measuring of systolic blood pressure, diastolic blood pressure and heart rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 gram of therapeutic gel is applied to the wrist overlying radial pulse (centered approximately 1 cm proximal to the radial styloid process) at least half an hour before arterial puncture.

Category

Prevention

2

Description

Control group: 1 gram of placebo gel is applied to the wrist overlying radial pulse (centered approximately 1 cm proximal to the radial styloid process) at least half an hour before arterial puncture.

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Tehran Heart Center

Full name of responsible person

Azita Hajhossein Talasaz

Street address

North Kargar Ave.

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Phone

+98 21 8802 9600

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

16 Azar Ave., Keshavarz Blvd.

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Azita Hajhossein Talasaz

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

The data like PCI check list and effects of therapeutic gel will be published in form of article

When the data will become available and for how long

At the end of study and after publication

To whom data/document is available

Scientific researchers

Under which criteria data/document could be used

For more researches

From where data/document is obtainable

Azita Hajhossein Talasaz

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

After acceptance by Azita Hajhossein Talasaz

Comments