

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Evaluation of the efficacy of topical lidocaine on radial spasm in patients underwent trans-radial angiography

#### Protocol summary

##### Study aim

Evaluation of the efficacy of topical lidocaine on radial spasm in patients underwent trans-radial angiography

##### Design

Phase 2 randomized double-blinded placebo parallel clinical trial on 276 patients Randomization using RandoMaization.com

##### Settings and conduct

This study will perform in the heart ward of Ghaem Hospital in Mashhad. Patients are randomly assigned to Lidocain and placebo groups. Patients and the main researcher are unaware of groups assignation.

##### Participants/Inclusion and exclusion criteria

Patients who underwent trans-radial angiography; Consent to admission to the study; Age over 18 years

##### Intervention groups

Intervention group: Patients who underwent trans-radial angiography and topical Gel of Lidocain will be applied 30 minutes before PCI. Placebo group: Patients who underwent trans-radial angiography and topical Gel of placebo will be applied 30 minutes before PCI.

##### Main outcome variables

Radial artery spasm during procedure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220516054874N7**

Registration date: **2022-12-07, 1401/09/16**

Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**

Update count: **0**

##### Registration date

2022-12-07, 1401/09/16

#### Registrant information

##### Name

Vafa Baradaran Rahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3800 2301

##### Email address

baradaranrv@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2024-12-21, 1403/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Evaluation of the efficacy of topical lidocaine on radial spasm in patients underwent trans-radial angiography

#### Public title

Efficacy of topical lidocaine on radial spasm

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients who underwent radial angiography Consent to admission to the study Age more than 18 years old

##### Exclusion criteria:

Allergy to topical lidocaine

#### Age

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **276**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The blocked randomization method is used. The volume of each block will be four. Then the list of blocks is written and numbers assigned to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 69 blocks according to the sample size of 276. Then random numbers between 1 and 69 are selected according to the randomization site Randomization.com and finally, the treatment allocation list is determined based on the random numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Using sealed envelopes Due to the use of a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups. Finally, after analyzing the data, the researcher who prepared the packages will reveal the codes A and B.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of School of Medicine, Mashhad University of Medical Sciences

**Street address**

Faculty of Medicine, Ferdowsi University complex, Azadi Sq., Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Approval date**

2022-10-25, 1401/08/03

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1401.454

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

Angina pectoris

**ICD-10 code**

I20

**ICD-10 code description**

Angina pectoris

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

The incidence of 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 vasodilator 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.

**Secondary outcomes****1****Description**

Patient pain

**Timepoint**

During radial canulation

**Method of measurement**

According to the VAS scale (0-10; 0 is the least and 10 is the most pain)

**2****Description**

Sympathetic system response

**Timepoint**

Before and after angioplasty

**Method of measurement**

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

**Intervention groups****1****Description**

Intervention group: Patients who underwent trans-radial angiography and 1 gram of lidocaine gel is applied to the wrist overlying radial pulse (centered approximately 1 cm proximal to the radial styloid process) 30 minutes before arterial puncture.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Patients who underwent trans-radial angiography and 1 gram of placebo gel is applied to the wrist overlying radial pulse (centered approximately 1 cm proximal to the radial styloid process) 30 minutes before arterial puncture.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ghaem Hospital in Mashhad

**Full name of responsible person**

Dr. Mostafa Dastani

**Street address**

Ghaem hospital, Ahmadabad Blvd, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

13944-91388

**Phone**

+98 51 3801 2739

**Email**

DastaniM@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Majid Ghayour-Mobarhan

**Street address**

Qurashi Building, Next to Hoveyzeh Cinema,  
University Street, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 1538

**Email**

Ramresearch@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Vafa Baradaran Rahimi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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Ghaem hospital, Ahmadabad Blvd, Mashhad

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**Phone**

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**Person responsible for scientific inquiries**

**Contact**

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Mashhad University of Medical Sciences

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Dr. Vafa Baradaran Rahimi

**Position**

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**Latest degree**

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**Other areas of specialty/work**

Medical Pharmacy

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Ghaeem hospital, Ahmadabad Blvd, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**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