

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The Effectiveness of topical anesthesia in the prevention of radial artery spasm and pain reduction before transradial approach coronary angiography

#### Protocol summary

##### Study aim

The Effectiveness of topical anesthesia in the prevention of radial artery spasm and pain reduction before transradial approach coronary angiography

##### Design

Two arm parallel group randomised, Double blinded clinical trial with 200 patients. For randomization, permutation block stratified randomization method was used.

##### Settings and conduct

This randomized study will be performed on 200 women Angiography candidates in the Ali Ibn Abitaleb Hospital in Zahedan. patients will be divided into the two intervention and Control groups. The data collection tool is through a data collection checklist and Clinical observations. In this double blinded clinical trial with control group, randomization will be performed by permutation block method.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Candidates for radial Angiography: Over 18 years old ; Exclusion Criteria History of same side Angiography in previous Procedures ; Reynaud Syndrome; ESRD; Allergy to topical Analgesic; Lack of Radial Pulse; patient`s dissatisfaction to participate in the study

##### Intervention groups

Intervention group: 2.5 gram of therapeutic ointment Xyla-P is applied to the wrist overlying radial pulse (centered 1 cm proximal to the radial styloid process) half an hour before arterial puncture. Control group: 2.5 gram of Placebo ointment is applied to the wrist overlying radial pulse (centered 1 cm proximal to the radial styloid process) half an hour before arterial puncture.

##### Main outcome variables

The Visual Analogue Scale (VAS) : The occurrence of spasm following radial angiography

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120817010617N9**

Registration date: **2022-11-04, 1401/08/13**

Registration timing: **prospective**

Last update: **2022-11-04, 1401/08/13**

Update count: **0**

##### Registration date

2022-11-04, 1401/08/13

##### Registrant information

##### Name

morteza Sedaghat Kia

##### Name of organization / entity

zaums

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 1244 9540

##### Email address

morimedico@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2023-12-22, 1402/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The Effectiveness of topical anesthesia in the prevention of radial artery spasm and pain reduction before transradial approach coronary angiography

### Public title

Effect of topical anesthesia in transradial approach coronary angiography

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Candidates for radial Angiography Over 18 years old

#### Exclusion criteria:

History of same side Angiography in previous Procedures  
Reynaud Syndrome ESRD Allergy to topical Analgesic  
Lack of Radial Pulse patient`s dissatisfaction to participate in the study

### Age

From **18 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **200**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Random assignment of patients to two groups will be done by permutation block stratified randomization method. Eligible patients will be classified respectively. based on 10 blocks (consisting of two groups A and B and two repetitions for each) patients will be randomly selected from all possible modes of permutations, and will be assigned to the desired group.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this clinical trial, the Double Blinding method will be used. So that the Patients and practitioners will not be aware of the intervention. and the nurse is in charge of the patient`s analgesics without the knowledge of the researcher.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

##### Street address

Dr.Hesabi Square

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

#### Approval date

2022-08-28, 1401/06/06

#### Ethics committee reference number

IR.ZAUMS.REC.1401.199

## Health conditions studied

### 1

#### Description of health condition studied

Acute coronary syndrome

#### ICD-10 code

I24.9

#### ICD-10 code description

Acute ischemic heart disease, unspecified

## Primary outcomes

### 1

#### Description

The Visual Analogue Scale (VAS)

#### Timepoint

After Angiography

#### Method of measurement

Visual Analogue Scale checklist

### 2

#### Description

The occurrence of spasm following radial angiography

#### Timepoint

During the Angiography Procedure

#### Method of measurement

See the patient's angiogram during the procedure

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 2.5 gram of therapeutic ointment

Xyla-P (Iranian Tehran Chemie inc.) is applied to the wrist overlying radial pulse (centered 1 cm proximal to the radial styloid process) half an hour before arterial puncture.

**Category**

Prevention

**2****Description**

Control group: 2.5 gram of Placebo ointment is applied to the wrist overlying radial pulse (centered 1 cm proximal to the radial styloid process) half an hour before arterial puncture.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ali-ebn Abi Taleb Hospital, Zahedan

**Full name of responsible person**

Neda Ehsan Zade

**Street address**

Zahedan Ali-ebn Abi Talib Hospital, Salamat boulevard, Dr.Hesabi square, Zahedan

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**Email**

n.ehsanzade@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr. Nour Mohammad Bakhshani

**Street address**

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zaums.research@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zahedan 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Neda Ehsan Zade

**Position**

Cardiology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
Neda Ehsan Zade  
**Position**  
Cardiology Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Cardiology  
**Street address**  
Hesabi sq.  
**City**  
Zahedan  
**Province**

## 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