

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)

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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

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

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

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Full name of responsible person

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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

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

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Other areas of specialty/work

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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