Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Local Warming of forearm on reducing of pain and spasm of Radial Artery During Coronary Angiography: A Randomized Clinical Trial

Protocol summary

Study aim
To evaluate the efficacy of local forearm warming in reducing pain and radial artery spasm during transradial coronary angiography.

Design
A randomized (time-based allocation), two-group, parallel, prospective clinical trial involving 118 patients.

Settings and conduct
Conducted at the Cath Lab of Hajar Hospital, Shahrekord University of Medical Sciences. This is an open-label (unblinded) study.

Participants/Inclusion and exclusion criteria
Age > 18 years; candidates for right transradial coronary angiography (stable CAD or stable NSTEMI/UA); SBP >100 mmHg; stable cardiac rhythm. Exclusion: Severe heart failure; active STEMI; history of right upper extremity surgery, trauma, or prior transradial angiography; unstable arrhythmia; coagulation disorders.

Intervention groups
Intervention Group: Local forearm warming (5–10 minutes, reaching 37.5°C–37.9°C) before puncture, combined with a 200 mcg intra-arterial nitroglycerin injection. Control Group: Routine standard care combined with a 200 mcg intra-arterial nitroglycerin injection.

Main outcome variables
Primary: Incidence and severity of radial artery spasm (RAS) evaluated via the 4-grade Rathore score. Secondary: Procedural pain severity (VAS score), vital signs fluctuations (SBP, DBP, HR, SpO2), requirement for supplementary medications, access-site crossover rate to the femoral artery,vasovagal rate and overall patient satisfaction.

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20201028049181N4**
Registration date: **2026-07-06, 1405/04/15**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-06, 1405/04/15**
Update count: **0**

Registration date
2026-07-06, 1405/04/15

Registrant information

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Pedram Babaee
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-07-06, 1405/04/15
Expected recruitment end date
2026-09-06, 1405/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Local Warming of forearm on reducing of pain and spasm of Radial Artery During Coronary Angiography: A Randomized Clinical Trial

Public title

Effect of forearm warming on reducing radial artery spasm and hand pain during coronary angiography

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged age 18 years old Candidates for diagnostic coronary angiography or elective/emergency uncomplicated percutaneous coronary intervention (PCI) via transradial access Patients with stable coronary artery disease (Stable CAD) or uncomplicated non-ST-elevation myocardial infarction / unstable angina (NSTEMI/UA) Systolic blood pressure > 100mmHg Normal sinus rhythm or stable asymptomatic arrhythmias. Ability to provide written informed consent. not given any inter-arterial vasodilator before starting angiography Feasibility of using the right radial artery based on clinical examination and standard or modified Allen's test.

Exclusion criteria:

Severe heart failure with NYHA functional class III or IV Acute myocardial infarction (Acute MI) including active STEMI or active NSTEMI at the time of presentation. History of traumatic injury or significant surgery in the right upper extremity that has disrupted the anatomy or function of the radial artery. History of previous angiography or intervention via the right radial artery Known coagulation disorders or consumption of medications with a high risk of bleeding, based on the investigator's judgment Inability of the patient to cooperate or failure to obtain informed consent Any concurrent clinical condition that, in the opinion of the principal investigator, affects patient safety or the validity of the study data Pregnancy or lactation. Systolic blood pressure < 100 mmHg Symptomatic bradycardia (HR < 50 bpm) Unstable arrhythmia (such as AF with uncontrolled RVR, Complete heart block, or VT)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **118**

Randomization (investigator's opinion)

Randomized

Randomization description

To prevent disruption in the routine workflow of the angiography unit and to minimize staff confusion, patient assignment is conducted using a time-based allocation method. On predefined days of the week, all eligible patients enrolled on that specific day receive a designated intervention. For instance, patients presenting on Mondays are assigned to the control group (receiving nitroglycerin), while patients presenting on Wednesdays are assigned to the intervention group (receiving nitroglycerin and local forearm warming). This allocation scheme remains fixed throughout the entire study period, and an equal ratio of patients between the two groups is maintained based on the number of sessions.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Hajar Hospital, University Headquarters, Parastar St., Kashani Blvd.

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Approval date

2026-06-23, 1405/04/02

Ethics committee reference number

IR.SKUMS.MED.REC.1405.085

Health conditions studied

1

Description of health condition studied

Radial artery spasm during coronary angiography

ICD-10 code

I73.9

ICD-10 code description

Peripheral vascular disease, unspecified

Primary outcomes

1

Description

Incidence and grade of radial artery spasm during the transradial coronary angiography

Timepoint

From the moment of catheter insertion until the end of the procedure

Method of measurement

The operator assesses radial artery spasm based on the occurrence of at least one of the following criteria: 1) Clear arm pain with a Visual Analogue Scale score

greater than or equal to 4, 2) Confirmed mechanical resistance during catheter movement, 3) Need for additional intra-arterial vasodilators, 4) Need to convert access site from radial to femoral due to spasm

Secondary outcomes

1

Description
Comparison of hemodynamic changes, including systolic blood pressure, diastolic blood pressure, heart rate, and blood oxygen saturation among the two study groups.
Timepoint
Measured at baseline (before drug injection), at the 1st minute, 5th minute, and then every 5 minutes until the end of the procedure, continuing up to 30 minutes after the start of angiography.
Method of measurement
Monitored and recorded using a standard patient monitoring device in the angiography suite. Systolic and diastolic blood pressures are measured in millimeters of mercury, heart rate in beats per minute, and blood oxygen saturation as a percentage via continuous pulse oximetry.

2

Description
Incidence of vasovagal reactions during the transradial procedure.
Timepoint
From the beginning of the catheterization until 5-10 minutes
Method of measurement
Diagnosed based on clinical symptoms and hemodynamic changes, including symptomatic hypotension (a decrease in systolic blood pressure of 20 mmHg or more compared to baseline) or symptomatic bradycardia, accompanied by symptoms such as sweating or nausea.

3

Description
Evaluation of the access-site crossover rate from radial to femoral artery access due to radial artery spasm
Timepoint
From the beginning of the catheterization procedure until its completion.
Method of measurement
Calculated as the percentage of patients in each treatment group who require switching the access site to the femoral artery due to severe or refractory radial artery spasm.

4

Description
Assessment of procedural pain intensity during the transradial procedure.
Timepoint
Immediately after the completion of the procedure, recording the overall pain experienced throughout the entire procedure.
Method of measurement
Pain intensity is measured using a 10-centimeter Visual Analogue Scale, where a score of 0 represents "no pain" and a score of 10 represents the "worst possible pain". The score is recorded based on the patient's self-report by a trained independent assessor.

Intervention groups

1

Description
Control group: Intra-arterial drug injection: Tng 200ug from a 5mg/5cc vial from Caspian Tamin Company. This drug is injected after the start of angiography
Category
Prevention

2

Description
Intervention group:Warming the forearm with a non-contact warmer for 5-10 minutes after sterilizing the hands along with intra-arterial drug injection: Tng 200ug from a 5mg/5cc vial from Caspian Tamin Company. This drug is injected after inserting the radial sheet.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital of Shahrekord Univesity of medical sciences
Full name of responsible person
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Cardiology

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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

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