Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

An investigation of local forearm heating on the pain intensity and hemorrhage of patients undergoing cardiac catheterization via radial artery at the time of withdrawal sheath: A pilot study

Protocol summary

Study aim

Determining of the effect of local forearm heating on the pain intensity and hemorrhage of patients Undergoing Cardiac Catheterization via Radial Artery at the Time of Withdrawal Sheath

Design

This study was designed as a phase 2 clinical trial with a control group of 50 patients in each group, in a double-blind, randomized manner, which CREATE A RANDOMISATION LIST program was used for randomization.

Settings and conduct

This study was conducted on 100 patients who are candidates for angiography and coronary angioplasty through the radial artery in the angiography department of Ayatollah Rouhani Hospital in Babol. For blinding, the sheaths were removed by people other than the present researcher and for data analysis, the studied groups were marked with alphabet labels.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65 years, indication of cardiac catheterization, non-emergency of cardiac catheterization. Exclusion criteria: history of previous catheterization through the radial artery, more than 3 catheter changes during the procedure, more than 3 attempts to puncture the artery

Intervention groups

In the intervention group, local heating of the hand with the Warm Touch device is performed for 3 minutes with hot air that has a temperature of 35-45 degrees centigrade from a distance of 20-30 cm. In the control group, the sheath is removed without any intervention.

Main outcome variables

Pain intensity; Bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220521054951N1**
Registration date: **2022-11-17, 1401/08/26**
Registration timing: **retrospective**

Last update: **2022-11-17, 1401/08/26**
Update count: **0**

Registration date

2022-11-17, 1401/08/26

Registrant information

Name
Atefeh Shamsian
Name of organization / entity
Shahid Rajaie Cardiovascular, Medical & Research Center
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-20, 1400/12/29

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
An investigation of local forearm heating on the pain intensity and hemorrhage of patients undergoing cardiac catheterization via radial artery at the time of withdrawal sheath: A pilot study

Public title
An investigation of Local Forearm Heating on the Pain Intensity and hemorrhage of Patients Undergoing Cardiac Catheterization via Radial Artery at the Time of Withdrawal Sheath

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Ability and willingness to cooperate with the researcher ability to speak and understand Persian language age of 18 to 65 years indication of cardiac catheterization through the radial artery no emergency for cardiac catheterization no history of paralysis and hemiparesis no surgery on the hand no History of peripheral vascular diseases (diabetes) or peripheral neuropathy no mastectomy no vascular fistula in patients with kidney diseases
Exclusion criteria:
Patients who have undergone more than one radial artery catheterization patients who have had catheter replacement more than 3 times patients who have been punctured more than 3 times

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
After block randomization with a size of 6, the patients are divided into two groups of 30 intervention and control (by CREATE A RANDOMISATION LIST computer program).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahid Rajaei Cardiology Research Training Center
Street address
Tehran - Wali Asr St. (Aj) - next to Mellat Park - Niayesh Corner of Shahid Rajaei Cardiovascular Training, Research and Treatment Center
City
Tehran
Province
Tehran
Postal code
1995614331

Approval date
2022-07-15, 1401/04/24

Ethics committee reference number
IR.RHC.REC.1401.049

Health conditions studied

1

Description of health condition studied
Patients undergoing cardiac catheterization through the radial artery

ICD-10 code
Y84.0

ICD-10 code description
Cardiac catheterization as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Pain intensity

Timepoint
When leaving the sheet and an hour after that

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Hemorrage

Timepoint
When leaving the sheet and an hour after that

Method of measurement
view

Intervention groups

1

Description
Intervention group: Local heating of the forearm for 3 minutes by the Warm Touch device, COVIDEN-2013), before removing the arterial sheath.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol Ayatollah Rouhani Hospital
Full name of responsible person
Seyed Atefeh Shamsian Khairabadi
Street address
Ayatollah Rouhani Hospital, Ganj Afrooz St., Daneshgah Square, Babol
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mehdi Rajabnia
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Babol University of Medical Sciences; Ganj Afrooz Street
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Seyed Atefeh Shamsian Khairabadi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

Not applicable

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