

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Effect of Cryotherapy on Pain Intensity for Patients Undergoing Sheath Removal after Percutaneous Coronary Intervention: A Randomized Controlled Trial

Protocol summary

Study aim

To determine the effect of cryotherapy on pain intensity for patients undergoing arterial sheath removal after percutaneous coronary intervention.

Design

A randomized controlled trial design was employed to achieve the objectives. The parallel group is unblinded; 118 subjects will be assigned to join, divided into the study group and the control group.

Settings and conduct

This study was conducted at the Babylon Centers for Catheterization and Cardiac Surgery, in Al-Imam Sadiq Hospital in Babylon, Iraq. This study was conducted as an open-label (unblinded) study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Male and female adults (18 years of age and older) who volunteered to participate in the study. 2. Patients who underwent a single-catheter in the groin area. 3. The participants had to read and write. 4. They had not taken analgesics and were free from any hematoma or infection on the sheath site. Exclusion Criteria: 1. If the subjects declined to participate. 2. If patients suffer from severe visual impairment, a changed mental state, skin conditions linked to cold sensitivity (such as Raynaud's disease), diabetes, neuropathy, and burns, wounds, or other injuries at the sheath site. 3. Patients have a two-sheath area in the femur. 4. Individuals undergoing peripheral catheterization. 5. Patients have a hematoma and bleeding in the area of the femur artery.

Intervention groups

Firstly, the researcher collected data through the use of a questionnaire, and after removing the femoral sheath, the patient was put in a supine position, the insertion sheath site was covered with a tiny dressing, a cold bag of gel was covered with gauze, and pressure was applied by this cold bag at the sheath site for 20 minutes.

Main outcome variables

Relieve pain intensity after arterial sheath removal.

General information

Reason for update

Acronym

Effect of Cryotherapy on Pain Intensity (ECPI)

IRCT registration information

IRCT registration number: **IRCT20231101059928N1**

Registration date: **2024-01-06, 1402/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-06, 1402/10/16**

Update count: **0**

Registration date

2024-01-06, 1402/10/16

Registrant information

Name

Jameel Ali kadhem

Name of organization / entity

The University of Baghdad / College of Nursing

Country

Iraq

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-30, 1402/09/09

Expected recruitment end date

2024-03-01, 1402/12/11

Actual recruitment start date

2023-11-30, 1402/09/09
Actual recruitment end date
2024-03-01, 1402/12/11
Trial completion date
2024-03-01, 1402/12/11

Scientific title
Effect of Cryotherapy on Pain Intensity for Patients Undergoing Sheath Removal after Percutaneous Coronary Intervention: A Randomized Controlled Trial

Public title
Effect of Cold Application on Pain Intensity for Patients Undergoing Sheath Removal

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Male and female adults (18 years of age and older) who volunteered to participate in the study and signed a written consent form were eligible to be included. Patients who underwent a single-catheter coronary angioplasty through the femoral artery in the groin area. The participants had to read and write. They had not taken analgesics in the last few hours and were free from any hematoma or infection on the skin surrounding the sheath site.
Exclusion criteria:
If the subjects declined to participate, they were eliminated. If patients suffer from severe visual impairment, a changed mental state, skin conditions linked to cold sensitivity (such as Raynaud's disease), sensory-motor deficiency, diabetes, neuropathy, and scar tissue from burns, wounds, or other injuries surrounding the sheath site. Patients have a two-sheath area in the femur. Individuals undergoing peripheral catheterization. Patients have a hematoma and bleeding in the surrounding area of the femur artery before sheath removal.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **410**
Actual sample size reached: **118**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to maintain a transparent and scientific-based randomization process by using a probability-based (random sample) technique, participants (patients who underwent percutaneous coronary intervention) were divided into two groups: the intervention group and the control group. offering the sample two cards of various colors in a box and using a random allocation mechanism to choose one card to represent the research group. The intervention group is represented by the blue card, while

the control group is represented by the yellow card.

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
Research Ethical Approval Committee, at the College of Nursing.
Street address
Bab AL-Muadum
City
Baghdad
Postal code
14149

Approval date
2023-11-30, 1402/09/09

Ethics committee reference number
4441

Health conditions studied

1

Description of health condition studied
Patients who underwent percutaneous coronary intervention to treat coronary heart diseases.

ICD-10 code
I20-I25

ICD-10 code description
Ischemic heart diseases

Primary outcomes

1

Description
Relieve the pain intensity that occurs after arterial sheath removal.

Timepoint
When arterial sheath removal is immediately applied, an intervention for 20 minutes is applied, and the pain intensity is measured by the Visual Analogue Scale (VAS) after that.

Method of measurement
Questionnaire and Visual Analogue Scale (VAS).

Secondary outcomes

1

Description

Relieve the pain intensity that occurs after arterial sheath removal.

Timepoint

When arterial sheath removal is immediately applied, an intervention for 20 minutes is applied, and the pain intensity is measured by the Visual Analogue Scale (VAS) after that.

Method of measurement

Questionnaire and Visual Analogue Scale (VAS).

Intervention groups

1

Description

Intervention group: The questionnaire (which includes demographic and clinical data) will be given to the respondents as the first step in the intervention phase. After putting the patient in a supine position and removing the femoral sheath, a tiny dressing is applied over the insertion site, cold therapy is administered by applying pressure for 20 minutes, and the Visual Analogue Scale (VAS) is used to measure the pain intensity for the patients.

Category

Other

2

Description

Control group: The control group following participant completion of the questionnaire. Starting the sheath removal with standard procedures and without further intervention. Assess the level of pain intensity after 20 minutes by asking the patient to mark a point on the VAS (0-100 mm) line to indicate their level of pain and discomfort.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

The Babylon Center for Catheterization and Cardiac Surgery at AL-Imam Sadiq Hospital in Babylon, Ira

Full name of responsible person

Jameel Ali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

College of Nursing, University of Baghdad

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?

No

Title of funding source

The author of the trial is the funding source

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

College of Nursing, University of Baghdad

Full name of responsible person

Jameel Ali Al-Zuhary

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursing

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The researcher acknowledges that the scientific community has verified the study's results. As part of the sharing strategy, all relevant data will be made public by publishing the study report in respected, peer-reviewed publications.

When the data will become available and for how long

God willing, when the data collecting, analysis, and paper publication procedure is complete, all associated materials will be accessible for six months following publication.

To whom data/document is available

All the related files will be shared with any scientific interested parties.

Under which criteria data/document could be used

It may be used after seeking the author's permission and acknowledging his contribution.

From where data/document is obtainable

To get in touch with the author, use the business email address that will be provided along with the published work. jameel.ali2202m@conursing.uobaghdad.edu.iq

What processes are involved for a request to access data/document

N/A

Comments

Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfilling their academic endeavors.