Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Jameel Ali kadhem
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The University of Baghdad / College of Nursing
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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
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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.