

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Assessing the effect of local cold application over femoral sheath insertion site on low back pain and vascular complications of patients undergoing coronary angiography referred to Dr.Heshmat Educational and remedial center in Rasht in 2018-2019

Protocol summary

Study aim

determine Assessing the effect of local cold application over femoral sheath insertion site on low back pain and vascular complications of patients undergoing coronary angiography referred to Dr.Heshmat Educational and remedial center in Rasht

Design

This study is a randomized controlled clinical trial.The samples size is 110. Four random blocks were randomly allocated in two groups of intervention (cold pack) and control group, which is routine of the hospital (sand bag).

Settings and conduct

the study is conducted in patients undergoing coronary angiography referred to Dr.Heshmat Hospital in Rasht. Intervention group(cold pack) after covered with clear dressing a cold pack during 2 hours Will be applied on the place.Control group(sand bag):which is routine of the hospital included the use of sand bags is 3-4 kg to 4 hours

Participants/Inclusion and exclusion criteria

The inclusion criteria:Signing written informed consent, Older than 18 years old Not sensitive to cold. No active bleeding in the femoral area , Not experiencing lower back pain , Ability to understand persian language. No disorders psychiatric and seeing or hearing and time and place orientation .No history of treatment with thrombolytic drugs less than 6 monts, natural range of coagulation tests results.No use sedative duration 24 hourse exclusion criteria : The occurrence of conditions that may lead to impairment in the care process. diastolic or systolic blood pressure higher than 110 and 190 mm Hg

Intervention groups

Intervention group(cold pack): immediately after covered with clear dressing, a cold pack with a temperature of 15 to 18 °C during 2 hours(any period for 20 minutes with

10 minute intervals) Will be applied on the place Control group(sand bag): receive routine care included the use of sandbags is 3-4 kg to 4 hours

Main outcome variables

vascular complications and low back pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180701040297N1**

Registration date: **2019-01-24, 1397/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-24, 1397/11/04**

Update count: **0**

Registration date

2019-01-24, 1397/11/04

Registrant information

Name

Nazila Javadi-Pashaki

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 2088

Email address

n.javadi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30
Expected recruitment end date
2019-04-18, 1398/01/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effect of local cold application over femoral sheath insertion site on low back pain and vascular complications of patients undergoing coronary angiography referred to Dr.Heshmat Educational and remedial center in Rasht in 2018-2019

Public title
Assessing the effect of local cold application over femoral sheath insertion site on low back pain and vascular complications of patients undergoing coronary angiography

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Signing written informed consent Older than 18 years old Perform angiography via femoral artery Not sensitive to cold No active bleeding in the femoral area during the procedure and before the catheter withdrawal Not experiencing lower back pain before hospitalization Ability to understand persian language No psychiatric disorders No any problems with seeing or hearing and proper time and place orientation No history of treatment with thrombolytic drugs and bleeding disorder for less than 6 monts Having a natural range of coagulation tests results in a pre-angiographic case No use sedative duration 24 hourse

Exclusion criteria:

The occurrence of any conditions that may lead to impairment in the care process diastolic or systolic blood pressure higher than 110 and 190 mm Hg

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Four random blocks were randomly allocated in two groups of intervention (cold pack) and control group, which is routine of the hospital (sand bag). At the beginning of the study, 41 random blocks are selected based on different patches. In this random block, a lacquer envelope They are placed in the heart research center of Dr. Heshmat Hospital in Rasht. On the basis of

daily visits, after the study, the blocks are hidden from the envelope, and according to the corresponding block of the day, patients are assigned randomly in one of the intervention groups and the group.

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 Guilan University of Medical Sciences

Street address

Eastern Shahid Beheshti Boulevard, Vice Chancellor for research of Guilan University of Medical Sciences

City

Rasht

Province

Guilan

Postal code

93345-41938

Approval date

2018-12-16, 1397/09/25

Ethics committee reference number

IR.GUMS.REC.1397.340

Health conditions studied

1

Description of health condition studied

Angiography

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Vascular complication

Timepoint

Immediately after covered with clear dressing every 15 minute in first hour every 30 minute in the second hour and every hour to six hours

Method of measurement

A mount of bleeding is measured with weight of blood loaded gauze by balance with Milliliter. The borders of hematoma measures palpable mass on angiography

puncture site which measured by transparent ruler and ecchymosis any color change (blue purple) considered to be.

Secondary outcomes

1

Description

Back pain

Timepoint

Immediately after covered with clear dressing ,4,6 and 24 after angiography procedure

Method of measurement

Visual analogue scales (VAS)

Intervention groups

1

Description

Intervention group: The patients in the intervention group are, immediately after covered with clear dressing, a cold pack with a temperature of 15 to 18 °C during 2 hours(any period for 20 minutes with 10 minute intervals) Will be applied on the place

Category

Prevention

2

Description

Control group: The patients will receive routine care included the use of sandbags is 3-4 kg to 4 hours

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Teaching Hospital

Full name of responsible person

Nazila Javadi

Street address

Dr. Heshmat Rasht Hospital, Masala Square, Baniyan St

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3361 8177

Email

n.javadip@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Deputy of Guilan University of Medical Sciences

Full name of responsible person

Shadman Nemati

Street address

Namjou St., shahid siadati .,Research and Technology Deputy of Guilan University of Medical Sciences

City

Rasht

Province

Guilan

Postal code

39841-41469

Phone

+98 13 3333 5820

Fax

+98 13 3333 6395

Email

research@gums.ac.ir

Web page address

<http://www.gums.ac.ir/research/303/%d8%b5%d9%81%d8%ad%d9%87-%d8%a7%d8%b5%d9%84%db%8c.aspx>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research and Technology Deputy of Guilan 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

Rasht University of Medical Sciences

Full name of responsible person

Fariba Abrahimi

Position

Postgraduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

College of Nursing and Midwifery, Student street, Dr Beheshti ave, Rasht, Guilan, Iran

City

Rasht

Province

Guilan

Postal code

39841-41469

Phone

+98 13 3355 5056

Fax

+98 13 3355 0097

Email

faribaebrahimishalmani65@Yahoo.com

Web page address

<http://www.gums.ac.ir/nmr>

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Nazila Javadi

Position

Acaedemic Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

College of Nursing and Midwifery, Student street, Dr Beheshti ave, Rasht, Guilan, Iran

City

Rasht

Province

Guilan

Postal code

39841-41469

Phone

+98 13 3355 5056

Fax

+98 13 3355 0097

Email

n.javadip@gmail.com

Web page address

<http://www.gums.ac.ir/nmr>

Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Nazila Javadi

Position

Acaedemic Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

College of Nursing and Midwifery, Student street, Dr Beheshti ave, Rasht, Guilan, Iran

City

Rasht

Province

Guilan

Postal code

39841-41469

Phone

+98 13 3355 5056

Fax

+98 13 3355 0097

Email

n.javadip@gmail.com

Web page address

<http://www.gums.ac.ir/nmr>

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total of data is Shareable after unidentifiable the people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Meta analysis

From where data/document is obtainable

Dr Nazila Javadi Guilan University of Medical Sciences.

Shahid Beheshti Nursing and Midwifery School of Rasht

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

contact by email

Comments