

# 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

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+98 13 3355 0097

**Email**

faribaebrahimishalmani65@Yahoo.com

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<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

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n.javadip@gmail.com

**Web page address**

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

Rasht University of Medical Sciences

**Full name of responsible person**

Nazila Javadi

**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Web page address**

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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**

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**