

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of ice packs on hematoma prevention in radial artery angiography in patients with acute coronary syndrome

Protocol summary

Study aim

The effect of ice compress on prevention of hematoma in radial artery angiography in patients with acute coronary syndrome

Design

This study will be a clinical trial with a control group, with a parallel group, without blinding, randomized on 120 patients. To assign people to two groups, a block randomization method with a block size of 4 will be used

Settings and conduct

The study population will be patients undergoing radial angiography in Quds Arak Hospital. 120 samples will be selected based on the inclusion and exclusion criteria of the study. By random allocation method with blocking and without blinding into 2 groups: intervention group 1 which ice compress with dimensions of 5*10 cm, weighing 100gr and covered with sterile gauze, in 2 stages, the 1st stage before removing the transparent cuffed bracelet and the 2nd stage immediately after removing the transparent cuffed bracelet. In each stage, the duration of using the ice compress will be 20 minutes. Intervention group 2 is the control group and they receive the usual care of the hospital (holding up the hand that has undergone angiography).

Participants/Inclusion and exclusion criteria

Entry conditions: informed consent, age 18-80 years, platelets in the normal range, no sensitivity to cold;
Non-entry conditions: abnormal bleeding from the angiography site, non-cooperation

Intervention groups

Intervention group 1 includes patients undergoing radial angiography, who receive an ice compress covered with sterile gas in 2 stages in order to perform the intervention. Intervention group 2 (control group) includes patients undergoing radial angiography who receive the usual care of the hospital (holding the arm that has undergone angiography)

Main outcome variables

size of the hematoma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221030056340N1**

Registration date: **2022-12-07, 1401/09/16**

Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**

Update count: **0**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name

Mahbobeh Rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5245 2650

Email address

mahbob.r72@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-16, 1401/09/25

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ice packs on hematoma prevention in radial artery angiography in patients with acute coronary syndrome		Other design features	
Public title	"Effect of Ice Compress on Hematoma Control"	Secondary Ids	empty
Purpose	Prevention	Ethics committees	
Inclusion/Exclusion criteria	Inclusion criteria: Ability to Give Informed Consent Age 18-80 Years Radial Angiography and Having a Cuffed Bracelet Platelets within the normal range INR<1.8 Not having Coagulation Problems No Addiction No History of Angiography in the Past Year Not Receiving Streptokinase or Retplase in the Last Three Months Not Sensitive to Cold Exclusion criteria: Unusual Bleeding from the Angiographic Site Non-cooperation and Withdrawal from the Study	1	
Age	From 18 years old to 80 years old	Ethics committee	
Gender	Both	Name of ethics committee	Ethics committee of Arak University of Medical Sciences
Phase	N/A	Street address	No. 20 , Moallem Ave., Vincheh., Mobarakeh
Groups that have been masked	No information	City	Mobarakeh
Sample size	Target sample size: 120	Province	Isfahan
Randomization (investigator's opinion)	Randomized	Postal code	8499115431
Randomization description	Sealed Envelope online site will be used for the randomization process. Regarding the method of randomization, at the beginning of the study, using the above site, a random sequence of 120 cases was generated using the block method, which included 60 intervention cases and 60 control cases, and this list was kept with the epidemiologist colleague (consultant professor).After examining the entry criteria of each participant, and their eligibility, to decide on the placement of that person in each of the groups, the student contacted the advisor and based on the randomization sequence list for that person. A decision will be made.This procedure will be done for all participants (120 people) until the end, which will lead to the division of people into two completely equal and random groups, and this will keep the random sequence hidden from the patient (student), which shows the concept of concealment. Or Concealment is random in the allocation process. In addition, as mentioned above, the selection of each of 120 people for the intervention and control groups is based on the randomization sequence list and with the opinion of the epidemiologist (consultant professor).	Approval date	2022-09-11, 1401/06/20
Blinding (investigator's opinion)	Not blinded	Ethics committee reference number	IR.ARAKMU.REC.1401.197
Blinding description		Health conditions studied	
Placebo	Not used	1	
Assignment	Parallel	Description of health condition studied	Radial Artery Angiography
		ICD-10 code	I97.610
		ICD-10 code description	Postprocedural hemorrhage and hematoma of a circulatory system organ or structure following a cardiac catheterization
		Primary outcomes	
		1	
		Description	Prevention of hand hematoma after radial angiography
		Timepoint	The area of the radial artery will be evaluated immediately after removing the cuffed transparent cuff, 2, 4, 6 hours after removing the transparent cuff and the morning after the angiography.
		Method of measurement	The Christensen scale is used as a scale to evaluate the efficiency of hemostasis methods by evaluating the incidence of hematoma at different hours after the procedure.
		Secondary outcomes	empty

Intervention groups

1

Description

Intervention group: In order to perform the intervention, an ice compress (from Sarma Zar company) with dimensions of 10 x 5 cm, weighing 100 grams and covered with sterile gauze, in two stages, the first stage before removing the cuffed transparent bracelet and the second stage The cuffed transparent bracelet will be used immediately after leaving. In each stage, the duration of using the ice compress will be twenty minutes. Before and after the intervention, hematoma formation or non-formation, its dimensions and diameter will be measured.

Category

Prevention

2

Description

Control group: Holding up the arm undergoing radial angiography.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Quds Arak Specialized and Subspecialized Hospital

Full name of responsible person

Mahboubeh Rajabi

Street address

Palestine Street, Quds Arak Specialized and Subspecialized Hospital

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Markazi

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mehdi Salehi

Street address

No. 20 , Moallem Ave., Vinchek

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Isfahan

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mahboubeh Rajabi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

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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

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

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