

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the complications of two hemostasis methods (classic and patent) in patients undergoing transradial coronary angiography

Protocol summary

Study aim

To compare the complications of two hemostasis methods (classic and patent) after transradial coronary angiography

Design

Clinical trial consists of two parallel groups, nonblinded, randomized

Settings and conduct

Location: BU-ALI Hospital, Qazvin, Iran. The number of 234 patients undergo transradial angiography. After that, the patients are randomly divided to 2 equal groups for hemostasis. In the first group, hemostasis is performed by classic method, and it is done by patent method in second group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate for coronary arteries angiography
Exclusion criteria: Unstable hemodynamic; Severe renal failure; Fracture of the bones wrist; Raynaud disease; Carpal tunnel syndrome; Coagulation disorders

Intervention groups

To perform homeostasis, in first group, classic method is applied and in second group, patent method is applied.

Main outcome variables

Incidence of radial artery occlusion; Hemostasis time; Mean of pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210305050585N1**
Registration date: **2021-05-07, 1400/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-07, 1400/02/17**

Update count: **0**

Registration date

2021-05-07, 1400/02/17

Registrant information

Name

Ahmad Kiarad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

dr.ahamdkiarad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the complications of two hemostasis methods (classic and patent) in patients undergoing transradial coronary angiography

Public title

Comparison of the complications of two hemostasis after transradial coronary angiography

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for transradial coronary arteries

angiography

Exclusion criteria:

Unstable hemodynamic Severe renal failure Fracture of the bones wrist Raynaud disease Carpal tunnel syndrome Coagulation disorders

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **234**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of individuals to study groups was done in a randomized block method using 4 blocks. This work was done with "https://app.studyrandomizer.com". In each block, there were 2 people belonging to group A and two people belonging to group B. In each block, number of treatment group and control group is equal and situation of each block with other block is different. With using opaque envelopes, sealed, sequentially numbered which recorded each of the random sequences created on a card and the cards are placed in the letter envelopes in order.

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 Qazvin University of Medical Sciences

Street address

Shahid Beheshti Blvd

City

Qazvin

Province

Qazvin

Postal code

1391134156

Approval date

2020-04-25, 1399/02/06

Ethics committee reference number

IR.QUMS.REC.1399.022

Health conditions studied

1

Description of health condition studied

Homeostasis methods in coronary arteries angiography

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes

1

Description

Incidence of radial artery occlusion

Timepoint

2, 4 and 6 hours after angiography

Method of measurement

Clinical examination

Secondary outcomes

1

Description

Hemostasis time

Timepoint

After radial artery sheath removal until cession of bleeding

Method of measurement

Based on minute

2

Description

Mean of pain score

Timepoint

Immediately, 1 hour and 4 hours after angiography

Method of measurement

Based on VAS scale

Intervention groups

1

Description

Intervention group: In classic hemostasis method, homeostasis is performed by using an inflatable air filled wrist bracelet named as TR band at the distal forearm and radial artery site. At first, TR cuff is blowing with 15 cc of air until the radial artery blood flow was completely stopped. When primary hemostasis is occurred, TR cuff pressure is reduced and the band is removed.

Category

Treatment - Other

2

Description

Intervention group: In patent hemostasis method,

homeostasis is performed by using an inflatable air filled wrist bracelet named as TR band at the distal forearm and radial artery site. At first, TR cuff is blowing with 15 cc of air until the radial artery blood flow was completely stopped. After that, TR cuff pressure is reduced (in about 10 cc air) until a little bit of blood leakage and patient was placed under supervision as long as primary hemostasis.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bu-Ali Sina Hospital

Full name of responsible person

Ahmad kiarad

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Department of Cardiology, Bu-Ali Sina Hospital, Bu-Ali Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

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?**

Yes

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Ahmad Kiarad

Position

Resident of cardiology

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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

Qazvin University of Medical Sciences

Full name of responsible person

Majid Hajikarimi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

Resident of cardiology

Latest degree

Medical doctor

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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Non-identifiable patient data including patient information and analysis in journal publications or sending to academic researchers

When the data will become available and for how long

After publishing the article according to journal rules

To whom data/document is available

Academic Researchers

Under which criteria data/document could be used

For similar researches

From where data/document is obtainable

Corresponding authors

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

Request to corresponding author email

Comments