Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of coronary angiography and percutaneous coronary intervention via left distal radial artery versus femoral artery in post coronary artery bypass grafting patients; A pilot study

Protocol summary

Study aim

Comparison of angiography and coronary interventions through left distal radial artery and femoral artery in patients with history of coronary artery bypass graft surgery

Design

1:1 randomized unblinded clinical trial, with parallel groups, on 60 patients (30 in each group) using table of random numbers.

Settings and conduct

This prospective clinical trial will be performed at Tehran Heart Center in 2020. For this purpose, all patients with a history of coronary artery bypass grafting who are referred to this center for cardiac catheterization will be evaluated. Patients are 1:1 randomly divided into two groups of radial and femoral access which is based on random numbers given by the computer. The procedures will be performed by the Interventional Cardiology Fellowship. Finally, A questionnaire will be filled for each patient and the data will be analyzed by SPSS software version 25 .

Participants/Inclusion and exclusion criteria

inclusion criteria: Age between 18 and 90 years, History of coronary artery bypass graft surgery, Clinical indication for angiography and or angioplasty, No contraindication for contrast agents Able to provide informed consent Normal Allen test Exclusion criteria: Vascular disorder that makes it difficult to access the femoral or radial arteries

Intervention groups

In the first intervention group, coronary angiography or angioplasty is performed through catheterization of the femoral artery and in the second intervention group, coronary angiography or angioplasty is performed through radial artery catheterization.

Main outcome variables

Contrast volume; Fluoroscopic time; Vascular complications after the procedure at the site of the sheath implantation; Total procedure time; amount of radiation received, amount of heparin; vascular spasm in radial method; Number of wire and catheter used

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200712048083N1**
Registration date: **2022-02-05, 1400/11/16**
Registration timing: **retrospective**

Last update: **2022-02-05, 1400/11/16**
Update count: **0**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

Lale Farzadi niaki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of coronary angiography and percutaneous coronary intervention via left distal radial artery versus femoral artery in post coronary artery bypass grafting patients; A pilot study

Public title

Coronary angiography via left distal radial artery vs femoral artery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 90 years History of coronary artery bypass graft surgery clinical indication for coronary and graft angiography and/or intervention No contraindication for contrast agents Able to provide informed consent Normal Allen test

Exclusion criteria:

Vascular disorder that makes it difficult to access the femoral or radial arteries

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into into two groups of radial and femoral access by 1:1 simple individual randomization method based on a table of random numbers created by a computer to carry out allocation concealment. Randomization was performed using "www.random.org" list generator.

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

Cardiovascular Ethics Committee of Tehran Heart Center

Street address

Tehran Heart Center , north karegar st,Tehran Town

City

tehran

Province

Tehran

Postal code

۱۳۱۳۸۱۴۱۱۷

Approval date

2020-06-20, 1399/03/31

Ethics committee reference number

IR.TUMS.THC.REC.1399.006

Health conditions studied

1

Description of health condition studied

Angiography/angioplasty of coronary arteries

ICD-10 code

Z98.61

ICD-10 code description

Coronary angioplasty status

Primary outcomes

1

Description

Contrast volume

Timepoint

During procedure

Method of measurement

Using the container in the angiography room, the amount of Contrast volume consumption is calculated from the beginning to the end of the procedure.

2

Description

Fluoroscopic time

Timepoint

During procedure

Method of measurement

Using the calculations of the device used in the angiography room - Artis zee-siemens - Philips Aluuura FD10 & FD20

3

Description

Vascular complications after the procedure at the site of sheath implantation

Timepoint

During the procedure, after the procedure, and at the time of discharge

Method of measurement

Based on examination and use of Reverse barbeau test

4

Description
Total procedure time
Timepoint
During procedure
Method of measurement
From the time of lidocaine injection until the end of the procedure is recorded by the operator.

5

Description
Amount of radiation received
Timepoint
During procedure
Method of measurement
Based on the calculation of the angiography device (DAD and A.K)

6

Description
Amount of Heparin
Timepoint
During procedure
Method of measurement
Based on the amount of heparin unit injected into the patient during the procedure, which is recorded by the operator.

7

Description
Vascular spasm in radial method
Timepoint
During procedure
Method of measurement
Radial Spasm Grading due to physical exam then Matching with the corresponding algorithm

8

Description
Number of wire and catheters used
Timepoint
During procedure
Method of measurement
Number of wires and catheters consumed during the procedure recorded by the operator.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, patients undergo angiography or angioplasty through the left distal radial artery and the two groups are compared in terms of contrast volume, fluoroscopic time, vascular complications after the procedure at the site of sheath implantation, total procedure time, amount of radiation received, amount of heparin, vascular spasm in radial method, number of wire and catheter used.
Category
Treatment - Surgery

2

Description
Intervention group 2: In this group, patients undergo angiography or angioplasty through the femoral artery and the two groups are compared in terms of contrast volume, fluoroscopic time, vascular complications after the procedure at the site of sheath implantation, total procedure time, amount of radiation received, amount of heparin, vascular spasm in radial method, number of wire and catheter used.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Yaser Jenab
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Lale Farzadi Niaki
Position
Cardiac Intervention Fellowship Assistant
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Specialist
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Person responsible for updating data

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Specialist
Other areas of specialty/work
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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