

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of intravenous heparin versus intra-arterial heparin on radial artery blockage during myocardial catheterization via radial access.

Protocol summary

Study aim

The effect of intravenous heparin versus intra-arterial heparin on radial artery occlusion during coronary catheterization via radial access.

Design

The study is a double-blind, parallel group, randomized clinical trial. It is single-center, with a concealed randomization method using computer-generated sequences. The study includes a sample size of 200 patients.

Settings and conduct

Diagnostic coronary angiography through central radial access at the Taleghani Health Education Center of Shahid Beheshti University of Medical Sciences. Intravenous patients will receive 50 units per/kg up to 5000 units of heparin. This group will receive heparin through the opposite arm's vein. The intra-arterial group will receive the same amount of heparin. Both groups receive normal saline serum from a different vein than drug injection. In this study, the angiographer won't know about the heparin injection.

Participants/Inclusion and exclusion criteria

Criteria for inclusion: 1. A candidate for coronary angiography 2. According to expert diagnosis, from the radial artery Criteria for exclusion: 1. A non-cardiac life-threatening condition 2. Instability of vital signs

Intervention groups

In the intravenous group, patients will be given heparin at a rate of 50 units per kilogram of body weight, up to a maximum of 5000 units. Heparin will be injected into this group via the opposite arm's peripheral vein. The intra-arterial group will also get the heparin via the arterial route's sheath. In both groups, normal saline will be administered through a vein other than the one used for medication injection.

Main outcome variables

Prothrombin Time, partial thromboplastin time (PTT), international normalized ratio (INR), Bleeding Time (BT), Incidence of RAO based on the Bandeau test, radial

artery occlusion based on Color Doppler sonography, and the amount of prescribed heparin.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220724055544N1**

Registration date: **2023-11-07, 1402/08/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-07, 1402/08/16**

Update count: **0**

Registration date

2023-11-07, 1402/08/16

Registrant information

Name

Saba Mahdiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8827 8055

Email address

mahdiani71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous heparin versus intra-arterial heparin on radial artery blockage during myocardial catheterization via radial access.

Public title

Comparison of intravenous and arterial heparin on improvement of radial artery occlusion during catheterization

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have referred to Taleghani Health Education Center of Shahid Beheshti University of Medical Sciences for diagnostic coronary angiography through radial access.

Exclusion criteria:

Shock Severe heart failure Unstable vital sign

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of Randomization: Block Design Unit of Randomization: Individual patients Tools Used in Randomization: Computer software designed for randomization, ensuring both randomness and allocation concealment. Random Sequence Building: The computer software will generate a random sequence to assign patients to one of the two treatment groups (intravenous heparin or intra-arterial heparin). Allocation Concealment: Allocation concealment should be carried out to ensure that the treatment assignments are not known to the researchers or participants until the moment of assignment, helping maintain the integrity of the randomization process.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants will be divided randomly in sealed sheets by someone who is uninformed of the study's specifics. The patients will be fully aware that they will be participating in a study, but not which category they will be assigned to. The operating room operator knows how to inject heparin, but the mechanism is set up in such a way that the doctor doing the procedure does not.

Furthermore, the raw data is not made available to the major authors until after the statistical analysis and determination of the outcomes. Following that, participants in the study will be blinded to the type of procedure used in terms of outcomes. The person in charge of monitoring data collection will be in charge of coordinating the operator, the people who follow up on the results, and the person in charge of the study statistics.

Placebo

Not used

Assignment

Parallel

Other design features

An aspect of our design is the consideration of potential age and gender differences in response to heparin. Additionally, we will assess the need for matching based on other relevant factors such as comorbidities, baseline cardiovascular risk factors, and medication use. If our sample size permits, we will match participants in both treatment groups to ensure that our findings account for these potential confounding variables, enhancing the study's validity and relevance.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Shahid Beheshti University of Medical Sciences

Street address

Kudakyar St.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-10-18, 1401/07/26

Ethics committee reference number

IR.SBMU.MSP.REC.1401.332

Health conditions studied**1****Description of health condition studied**

Radial artery occlusion (RAO)

ICD-10 code

S55.10

ICD-10 code description

Unspecified injury of radial artery at forearm level

2

Description of health condition studied

acute coronary syndrome

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

Radial artery occlusion

Timepoint

Barbeau test and arterial ultrasound are both performed 24 hours after the study to find the main result.

Method of measurement

Radial artery occlusion is measured by Barbeau criterion or arterial ultrasound.

Secondary outcomes

1

Description

The amount of heparin

Timepoint

The amount of heparin is measured by the operator during the operation and recorded immediately after.

Method of measurement

The operator's heparin usage is pooled and announced by unit.

2

Description

Prothrombin time

Timepoint

Immediately after the intervention

Method of measurement

Prothrombin time by the Fisher brand laboratory kit

3

Description

Partial Thromboplastin time (PTT)

Timepoint

Immediately after the intervention

Method of measurement

Partial Thromboplastin time by the Fisher brand laboratory kit

4

Description

International unit ratio (INR)

Timepoint

Immediately after the intervention

Method of measurement

International unit of dividing pt by the expected amount

of the person at the desired age

5

Description

Bleeding time

Timepoint

Immediately after the intervention

Method of measurement

Bleeding time by the bt kit of bt-labatory company

Intervention groups

1

Description

Intervention group: Heparin will be injected through the sheet in the arterial route at a dose of 50 units per kilogramme of body weight up to a maximum of 5000 units. Given the country's shortages, the desired heparin may come from Alborz Daru, Royan, Kimidaro, Caspian, or Iran Human.

Category

Treatment - Drugs

2

Description

Venous group: Heparin at a dose of 50 units per kilogram of body weight up to a maximum of 5000 units will be administered into the opposite hand's peripheral vein at no other time. Given the country's shortages, the needed heparin may come from Alborz Daru, Royan, Kimidaro, Caspian, or Iran Human.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

(Ayatollah) Taleghani Educational Hospital

Full name of responsible person

Saba Mahdiani

Street address

A-arabi St.

City

تهران

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Email

mahdiani71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Deputy of research and technology

Street address

Kudakyar

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9783

Email

info@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Esmail Gheidari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

A-arabi

City

تهران

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 9770

Email

dr.n.nobakht@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Esmail Gheidari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

A-arabi

City

تهران

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 9770

Email

dr.n.nobakht@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saba Mahdiani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

Gisha

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 8827 8055

Fax**Email**

mahdiani71@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

If the reviewers require it, a portion of the data containing the main outcome will be published.

When the data will become available and for how long

After gathering and analyzing data, most likely beginning in September 2024

To whom data/document is available

Applicants who do not plan to abuse, in the opinion of the responsible author. This information will be offered to

academic and scientific researchers who produce a résumé confirming that they have no conflicts of interest. If necessary, industrial companies can submit a request, and there are approved research projects that will be reviewed by the major writers.

Under which criteria data/document could be used

If the following requirements are met, free individuals will have access to information: 1. Authorship confirmation of the responsible author 2. Providing the reason for the request for raw data 3. No conflict of interest

From where data/document is obtainable

Corresponding author's work email Mahdiani@gmail.com

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

Emailing and publishing for possible answers and interviews

Comments