

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

A clinical trial to compare the fluoroscopy time of coronary catheterization via right radial artery by left emplacement catheter with left Judkins catheter in pseudo-arteria lusoria patient

Protocol summary

Study aim

A clinical trial to compare the fluoroscopy time of coronary catheterization via right radial artery by left emplacement catheter with left Judkins catheter in pseudo-arteria lusoria patient

Design

Forty patients who were candidates for angiography, clinical trial with control group, community based pragmatic, parallel group, single-blind, randomized using table of random numbers

Settings and conduct

Patients candidate for angiography at the Department of cardiology, Ghaem Hospital, Mashhad, Iran, were chosen. In this single-blind study, the participants were unaware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age higher than 20 years; patients candidate for angiography by Cardiologist; having hemodynamic stability; negative Allen's test. Exclusion criteria: History of coronary artery bypass graft (CABG); having percutaneous coronary intervention (PCI); upper extremity deformities; history of peripheral artery disease (PAD) of the upper extremities.

Intervention groups

Intervention group I: A 0.035-inch wire is entered into the right subclavian artery and in case of observing an angle of less than 70 degrees between the brachycephalic and the aortic arch and the diagnosis of pseudo-arteria lusoria, the left catheter emplacement will be used. Intervention group II: A 0.035-inch wire is entered into the right subclavian artery and in case of observing an angle of less than 70 degrees between the brachycephalic and the aortic arch and the diagnosis of pseudo-arteria lusoria, the left Judkins catheter will be used.

Main outcome variables

Evaluation and comparison of time of fluoroscopic since

catheterization entry into radial artery until laryngeal mask airway (LMA) engage between two intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180617040123N1**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Laya Valaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3858 3853

Email address

valaeil941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the fluoroscopy time of coronary catheterization via right radial artery by left emplacement catheter with left Judkins catheter in pseudo-arteria lusoria patient

Public title

The fluoroscopy time in pseudo-arteria lusoria patient

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Age higher than 20 years Patients candidate for angiography by Cardiologist Having hemodynamic stability Negative Allen's test

Exclusion criteria:

History of coronary artery bypass graft (CABG) Having percutaneous coronary intervention (PCI) Upper extremities deformities History of peripheral artery disease (PAD) of the upper extremities

Age

From **20 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Forty patients who were candidates for angiography at the Department of Cardiology in Ghaem Hospital, Mashhad, Iran, were randomly allocated using table of random numbers based on computer programs. To this end, a code is allocated to each of the participants to be assigned into one of the two groups of intervention or control.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients candidate for angiography at the Department of cardiology, Ghaem Hospital, Mashhad, Iran, were chosen. In this single-blind study, the participants were unaware of the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2017-11-08, 1396/08/17

Ethics committee reference number

lr.mums.fm.rec.1396.490

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

pseudo-arteria lusoria patient

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Time of fluoroscopic

Timepoint

Since catheterization entry into radial artery until laryngeal mask airway (LMA) engage

Method of measurement

Timer

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: A 0.035-inch wire is entered into the right subclavian artery and in case of observing an angle of less than 70 degrees between the brachycephalic and the aortic arch and the diagnosis of pseudo-arteria lusoria, the left catheter emplacement will be used.

Category

Diagnosis

2

Description

Intervention group: A 0.035-inch wire is entered into the right subclavian artery and in case of observing an angle of less than 70 degrees between the brachycephalic and the aortic arch and the diagnosis of pseudo-arteria lusoria, the left Judkins catheter will be used.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Laya Valae

Street address

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

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ValaeiL941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Laya Valaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Laya Valaei provides the analysis code to the applicants via email: bahadoripb901@mums.ac.ir

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

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments