

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of rotational angiography with standard (traditional) angiography in patients referred to the Cardiac Center affiliated to Qazvin University of Medical Sciences in 2020-2021

Protocol summary

Study aim

The aim of this study was to compare rotational angiography with standard (traditional) angiography in patients.

Design

In this clinical trial, 64 patients with inclusion criteria were included in the study. Patients were randomly divided into two groups of 32 patients. The first group is treated with standard (traditional) angiography and the second group is treated with rotational angiography. The study is a blind study and trial phase 3. Randomization is performed using random sequence generation software. In this way, information such as sample size and number of groups is given to the software and the software provides a table of random numbers, each of which is randomly assigned the letters A and B. In this study, A numbers in the standard (traditional) angiography group and B numbers in the rotational angiography group.

Settings and conduct

In this one-way blind clinical trial, 64 angiography candidates with admission requirements who referred to Bu Ali Sina Hospital in Qazvin, were admitted to the study. In this study, only the data analyzer is blind. For the purpose of blinding, no information about the type of angiographic procedure is available in the file available to the analyzer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years; Early diagnosis of coronary artery disease; Angiography through the right femoral artery. Exclusion criteria: dissatisfaction with this method; Emergency angiography; Hemodynamic disorders; The patient's high weight.

Intervention groups

In one group, angiography is performed by conventional method (traditional) and in the other group by rotation.

Main outcome variables

The amount of contrast agent injected; The amount of

radiation emitted; Fluoroscopic duration; Duration of the procedure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210215050365N1**

Registration date: **2021-06-01, 1400/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-01, 1400/03/11**

Update count: **0**

Registration date

2021-06-01, 1400/03/11

Registrant information

Name

Mohammadreza Kheiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 3036

Email address

afikhob56@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of rotational angiography with standard (traditional) angiography in patients referred to the Cardiac Center affiliated to Qazvin University of Medical Sciences in 2020-2021

Public title
Comparison of rotational angiography with standard (traditional) angiography

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years Early diagnosis of coronary artery disease Angiography through the right femoral artery
Exclusion criteria:
 Dissatisfaction with the procedure Emergency angiography Hemodynamic disorders The patient's high weight

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Due to the ease of use and cost savings in time, participants were divided into two groups using random sequence generation software. In this way, information such as sample size and number of groups is given to the software and the software provides a table of random numbers, each of which is randomly assigned the letters A and B. In this study, A numbers are in the standard (traditional) angiography group and B numbers are in the rotational angiography group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study was performed blindly. In this study, the data analyzer did not know the type of method used on patients.

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

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd

City

Qazvin

Province

Qazvin

Postal code

3415613911

Approval date

2020-02-10, 1398/11/21

Ethics committee reference number

IR.QUMS.REC.1398.308

Health conditions studied

1

Description of health condition studied

Angiography

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of contrast agent injected

Timepoint

After angiography

Method of measurement

Based on the amount of cc used by the operator

2

Description

The amount of radiation emitted

Timepoint

After angiography

Method of measurement

It is recorded by angiography device.

3

Description

Fluoroscopic duration

Timepoint

After angiography

Method of measurement

It is recorded by angiography device.

4

Description

It is recorded by angiography device.

Timepoint

After angiography

Method of measurement

It is recorded by angiography device.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rotational angiography

Category

Treatment - Surgery

2

Description

Control group: standard angiography (common)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina Hospital

Full name of responsible person

Mohammadreza Kheiri

Street address

Boo-Ali Hospital, Boo-Ali St., Qazvin

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Province

Qazvin

Postal code

3413786165

Phone

+98 28 3333 2931

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afikhob56@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Mohammad Mahdi Emamjomeh

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Vice chancellor for research, Qazvin University of

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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

Mohammadreza Kheiri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Specialist
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Person responsible for updating data

Contact

Name of organization / entity
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Resident
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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

No - There is not 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

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

The collected information is in the form of a questionnaire and is statistically analyzed.

When the data will become available and for how long

The start of the access period is one year after the results are published.

To whom data/document is available

For cardiologists and researchers working in academic institutions

Under which criteria data/document could be used

Users can evaluate the study path and process.

From where data/document is obtainable

For information, refer to Dr. Mohammad Reza Kheiri. The communication channels are in the following order: by e-mail to the address: afikhob56@gmail.com or refer to and contact the Bu Ali Sina Hospital in Qazvin at the address: Qazvin, Bu Ali Street. Phone: 33332930-028
Postal address: 86165 - 34137

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

After sending the e-mail, the requested information will be reviewed by the facilitator and the person responsible for the scientific response of the study. At your discretion, the requested information will be sent within 10 days after receiving the email.

Comments