

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Investigation the effect of intravenous midazolam on radial artery spasm during performing coronary angiography - Randomized double blinded placebo control clinical trial

Protocol summary

Study aim

Investigating the effect of intravenous Midazolam on radial artery spasm during coronary angiography, a double-blind randomized clinical trial with a placebo control.

Design

Clinical trial with control group, single center, with parallel groups, double-blind, randomized, phase 3 on 56 patients that candidate for elective coronary angiography. Random assignment of participants into two study and control groups is done using permuted block randomization technique.

Settings and conduct

This double-blind study will be conducted in Heshmat Hospital in Rasht. Subjects and evaluators are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who undergo elective coronary angiography through right radial artery access. Exclusion criteria: The exclusion criteria include the patients who don't confirm the informed constant and the use of arterial accesses other than the radial artery (including femoral, brachial, and left radial arteries). Also, patients with emergency condition, hemodynamic disorder, cardiogenic shock, history of allergy to any benzodiazepine, and history of severe respiratory problems were excluded from the study. Other exclusion criteria include pregnancy and lactating, history of AV fistula in the same hand, and patients who are not a good candidate to perform radial angiography.

Intervention groups

56 patients over 18 years of age who were candidates for coronary angiography electively during 2021-2022 will be included in the study. Half of the patients are injected with half a milligram of intravenous Midazolam (28) immediately before the start of the procedure.

Main outcome variables

The primary outcome includes the reduction of radial

artery spasm, which is divided into three components of the visual analogue scale, the measure of sympathetic stimulation (including increased SBP and increased HR during the procedure) and radial artery spasm.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220809055645N2**

Registration date: **2023-04-03, 1402/01/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-03, 1402/01/14**

Update count: **0**

Registration date

2023-04-03, 1402/01/14

Registrant information

Name

Fatemeh Baharvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation the effect of intravenous midazolam on radial artery spasm during performing coronary angiography – Randomized double blinded placebo control clinical trial

Public title
Effect of intravenous midazolam on radial artery spasm during performing coronary angiography

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who undergo elective coronary angiography through right radial artery access.
Exclusion criteria:
Patient dissatisfaction Use of arterial access other than right radial artery (including femoral, brachial and left radial artery) Emergency patients Hemodynamic disorder Cardiogenic shock History of allergy to benzodiazepine History of severe respiratory complications Pregnancy and lactation History of AV fistula in the same hand Patients who are not candidates for radial angiography

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of participants into two study and control groups is done using permuted block randomization technique. For random allocation in this study, 4 blocks of 28 blocks are used. Using the specialized software from the Sealed envelope online software, chains of random numbers from 1 to 6 are generated until the desired sample size is reached. The date and time of randomization will be recorded. Concealment is done using the Sealed envelope method. To apply the concealment of the randomization process from the sealed non-transparent questionnaires that are numbered in order, the questionnaires of each person will be opened only after confirming the eligibility criteria for entering the study and signing the consent form by the person.

Blinding (investigator's opinion)
Double blinded

Blinding description

In this study, in order to avoid bias in the study, the statistical expert, sequencing and distribution of patients into groups A and B is performed. Then, the type of intervention or using placebo for group A and B is done by someone outside the team of evaluators. Also, a colleague outside of the group is asked to put the original drug and the placebo, which have the same appearance and quality, in the required number in exactly the same, dark, and closed pockets; and name them as A and B based on the type of intervention or placebo and make it available to the plan executives. In this way, neither the study patients nor the moderators know about the intervention and placebo groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Guilan University of Medical Sciences
Street address
Namjoo
City
Rasht
Province
Guilan
Postal code
41446-66949
Approval date
2023-03-01, 1401/12/10
Ethics committee reference number
IR.GUMS.REC.1401.581

Health conditions studied

1

Description of health condition studied
Radial Artery Spasm
ICD-10 code
I70-I79
ICD-10 code description
Diseases of arteries, arterioles and capillaries

Primary outcomes

1

Description
Radial artery spasm
Timepoint

During and immediately after the completion of angiography

Method of measurement

The three components of the visual analogue scale are the measure of sympathetic stimulation (including SBP increase and HR increase during the procedure) and radial artery spasm.

Secondary outcomes

1

Description

Duration of the procedure

Timepoint

Immediately after the completion of angiography

Method of measurement

The time interval from the start of vein finding to the exit of the angiography sheet

2

Description

Duration of fluoroscopy

Timepoint

Immediately after the completion of angiography

Method of measurement

It is reported by the Siemens angiography device in the exam protocol section.

3

Description

Patient willingness to use radial access in the next possible angiography procedure

Timepoint

Immediately after the completion of angiography

Method of measurement

Ask the patient

Intervention groups

1

Description

Intervention group: Immediately before the start of the procedure, they are injected with half a milligram of intravenous Midazolam (28) from Caspian Pharmaceutical Company.

Category

Prevention

2

Description

Control group: Immediately before the start of the procedure, they are injected with half a milligram of normal saline.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Heart Hospital

Full name of responsible person

Fatemeh Baharvand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Guilan University of Medical Sciences

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Parastar

City

Rasht

Province

Guilan

Postal code

41937-13111

Phone

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Email

riasat@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Fatemeh Baharvand

Position

Assistant Professor of Interventional Cardiology

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Full name of responsible person

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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

Yes - There is 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

All data except personal information (name, contact number, file number) can be published.

When the data will become available and for how long

After publishing the results

To whom data/document is available

Available to service providers such as doctors and nurses.

Under which criteria data/document could be used

After obtaining permission from the project manager, the information will be usable.

From where data/document is obtainable

Project manager

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

By email to the project manager

Comments

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