

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Study of the effect of intra-arterial administration of nitroglycerin and labetalol on radial artery diameter and spasm in patients undergoing radial angiography

Protocol summary

Study aim

Comparison of the efficacy of intra-arterial administration of labetalol versus intra-arterial nitroglycerin in reducing radial angiography- induced spasm and their effect on radial artery diameter

Design

Double blind, randomized clinical trial in patients undergoing radial angiography

Settings and conduct

This study is a randomized double-blind clinical trial conducted in Mazandaran Heart Center. Eight-member blocks were defined based on block-randomization. Patients respectively enrolled into the blocks and entered blindly into labetalol or nitroglycerin groups based on defined codes. An angiographic specialist prescribes the medication to the patients based on block-randomization and the investigator recorded the data without knowing the type of prescribed medication. Statistical analysts also was unaware of the interventionist groups. First, the initial diameter of the radial artery was measured before medication administration. Then patients received intra-arterial nitroglycerin (150 micrograms) or intra-arterial labetalol (500 micrograms). Radial artery diameter was re-measured immediately after the medication administration, as well as at the end of the angiography. Any spasm and pain during the procedure was also recorded.

Participants/Inclusion and exclusion criteria

- Inclusion criteria: All patients over 18 years old are candidates for radial angiography - Exclusion criteria: History of radial artery use in previous procedures, Peripheral artery disease and Raynauds, Ejection fraction less than 40%, Heart rate at rest less than 55 beats per minute, Systolic blood pressure less than 90 mmHg, History of liver disease, History of allergy to labetalol or nitroglycerin, Dissatisfaction of the patient to participate

in the study

Intervention groups

1. Labetalol (500 microgram) 2. Nitroglycerin (150microgram)

Main outcome variables

1. Incidence of spasm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151109024975N11**

Registration date: **2019-01-06, 1397/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-30, 1398/03/09**

Update count: **1**

Registration date

2019-01-06, 1397/10/16

Registrant information

Name

Gohar Eslami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3695

Email address

g.eslami@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of intra-arterial administration of nitroglycerin and labetalol on radial artery diameter and spasm in patients undergoing radial angiography

Public title

Comparison of labetalol and nitroglycerin in radial angiography-induced spasm

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients over 18 years old are candidates for radial angiography

Exclusion criteria:

History of using radial artery during previous procedures
Peripheral vascular diseases Raynaud syndrome Ejection fraction <40% Heart rate at rest less than 55 Systolic blood pressure less than 90 mmHg History of liver disease History of labetalol or nitroglycerin allergy
Dissatisfaction patient to participate in the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, samples will be assigned to two groups by block randomization method. Eight-member blocks were created using random allocation software with sequential codes. Then, samples with inclusion criteria will randomly enter to the two groups according the codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, an angiographic specialist prescribes the drug to the patients based on block-randomization and the investigator records the data without knowing the type of prescribed drug. Statistical analysts will also be unaware of the interventionist groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Research Deputy of Mazandaran University of Medical Sciences, Moalem Square

City

Sari

Province

Mazandaran

Postal code

13534 - 47416

Approval date

2018-09-17, 1397/06/26

Ethics committee reference number

IR.MAZUMS.REC.1397.158

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

Radial angiography-induced spasm

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

The occurrence of spasm following radial angiography

Timepoint

During angiography

Method of measurement

See the patient's angiogram during the procedure

Secondary outcomes**1****Description**

Severity of pain caused by radial angiography

Timepoint

During angiography

Method of measurement

Patient observation and registration based on pain score

2

Description

Changing the diameter of the radial artery

Timepoint

During angiography

Method of measurement

Measuring arterial diameter with its own special software on the angiogram recorded on the computer

Intervention groups

1

Description

Intervention group: Initially, the diameter of the radial artery will be measured prior to administration of the drug. Then, the patients will receive intra-arterial labetalol (500 microgram) and the radial artery diameter will be re-measured immediately after the administration of the medication and at the end of the angiography. Any spasm (before medication administration, immediately after administration and at the end of procedure) and pain during the procedure will be recorded.

Category

Prevention

2

Description

Intervention group: Initially, the diameter of the radial artery will be measured prior to administration of the drug. Then, the patients will receive intra-arterial nitroglycerin (150microgram) and the radial artery diameter will be re-measured immediately after the administration of the medication and at the end of the angiography. Any spasm (before medication administration, immediately after administration and at the end of procedure)and pain during the procedure will be recorded.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh-zahra hospital Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Street address

Artesh Blvd - Center of the heart of Mazandaran

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3331 4086

Fax

+98 11 3332 4002

Email

g.eslami@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Moalem Square, Research Deputy of MazandaranUniversity of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3325 7230

Fax

+98 11 3326 1244

Email

g.eslami@mazums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Mazandaran University of Medical Sciences, Imam
Square, Three Way Joybar, Beginning of Valiasr
Highway

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3354 3695

Fax

+98 11 3354 3695

Email

g.eslami@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Postal code

48157-33971

Phone

+98 11 3354 3695

Fax

+98 11 3354 3695

Email

g.eslami@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Position

Assistant Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Mazandaran University of Medical Sciences, Imam
Square, Three Way Joybar, Beginning of Valiasr
Highway

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3354 3695

Fax

+98 11 3335 2725

Email

g.eslami@mazums.ac.ir

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