

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Safety and efficacy of intravenous nitroglycerine infusion in the prevention and control of arterial spasm in transradial coronary angiography

Protocol summary

Study aim

Safety and efficacy of nitroglycerin intravenous infusion on the prevention and control of arterial spasm in coronary angiography

Design

In this study, 100 heart patients selected for coronary anaesthesiology who have criteria for entering the study are selected. The allocation of the sample in the control and intervention group is done randomly so that using the randomization table, the chance of entering the intervention and control group is the same for all patients.

Settings and conduct

The patients of the angiography section of the heart of Shahid Rajaei, Tehran, have been sampled. Blocks are used for randomization. The routine care routine questionnaire includes: Angiography, vital signs monitoring, injection of lidocaine and nitroglycerin cocktails into the radial artery, subcutaneous injection of the arterial pancreas by the operator and injection of nitroglycerin plums at 200 µg after insertion of the injection line Gets

Participants/Inclusion and exclusion criteria

Strong radial pulse, hypertension above 10mA, age above 18 and less than 80, as well as a history of arterial disease, as well as a history of allergic to nitroglycerin compounds.

Intervention groups

The routine control group, including lidocaine and nitroglycerin cocktails, is injected subcutaneously into the radial artery, injected with nitroglycerin plums at 200 µg immediately after insertion of the shield. For the intervention group, in addition to receiving routine care, 10 min before the start of the pancreas, nitroglycerin infusion starts at a rate of 5 Kg / µg and every two minutes the dose is increased to 5 µg in order to reach the prescribed dose if the patient is tolerated.

Main outcome variables

1 - Pain in the pancreas 2- Nitroglycerin plums 3. Hemodynamic patient 4- Number of hours of pancreure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160515027905N2**

Registration date: **2019-02-18, 1397/11/29**

Registration timing: **retrospective**

Last update: **2019-02-18, 1397/11/29**

Update count: **0**

Registration date

2019-02-18, 1397/11/29

Registrant information

Name

Farahnaz Maleki

Name of organization / entity

Nursing

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

university

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of intravenous nitroglycerine infusion in the prevention and control of arterial spasm in transradial coronary angiography

Public title

efficacy of intravenous nitroglycerine infusion in the prevention of arterial spasm in transradial coronary angiography

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Referral of the patient to the hospital for coronary artery angiography Systolic blood pressure greater than 100 mm Allen positive test Awareness of the patient's time and space for measuring pain Age older than 18 and less than 80 years

Exclusion criteria:

Failure to cooperate in the collection of information Lack of proper access to radial artery The drop in the blood pressure of the patient, which makes him inadequate in his hemodynamics Loss of consciousness Sensitization to nitroglycerine or similar compounds Radial artery for angiography or other diagnostic treatments (vascular graft) A history of vascular disease, such as Reynaud, which affects the artery stenosis Use of oral pills containing nitroglycerin compounds in the last 4 hours

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomized vote is a block random method, an individual randomization unit, so that at the beginning of each day, one of the patients with an angiographic candidate who had the criteria for entering the study was numbered and using the randomization table, Each patient was randomly assigned to either intervention or control group. To conceal, the placebo is used for the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, for the control group, in addition to the routine activities, which included subcutaneous injection of lidocaine and nitroglycerin in the pancreter and the arterial nodule of nitroglycerin, 200 micrograms, nitroglycerin infusion was started 10 minutes before the pancreter, and in the control group, in addition to the routine measures In order to avoid the knowledge of the angiographic team, the intravenous infusion patient group starts a combination drug with an apparently similar appearance of nitroglycerin

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shaheed Rajaei Heart Therapy Research Center Tehran

Street address

Valiasar street. Shaheed Rajaei Heart Therapy Research Center Tehran

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Province

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Postal code

1995614331

Approval date

2017-10-23, 1396/08/01

Ethics committee reference number

Rhc.ac.ir.Rec.1395.28

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

coronary artery disease

ICD-10 code

I51.6

ICD-10 code description

cardiovascular disease NOS

Primary outcomes**1****Description**

Coronary artery spasm intensity during trans-radial angiography

Timepoint

Ten minutes before initiation of the angiographic procedure until the end of the coronary artery

Method of measurement

In order to measure patient pain in the pancreatic area and catheter pathway, a visual analogue scale is used and the gyre pressure gauge is used to check the effects of nitroglycerin.

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

Patient's pain and resistance to the passage of the wires and the catheter

Timepoint

The procedure time from the start of the pancreas to the end of the angiography

Method of measurement

Radar artery pancreatic time and during angiography

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

In the intervention group, 10 minutes before the radial artery pancreas, nitroglycerin infusion began with a dose of 5 micrograms, and with control of blood pressure and disease of the patient up to 5 microns, based on the weight of the patient. In the control group, a drug like nasal saline was used and minutes before the infusion of the drug in the control group begins. In this way, the operator will not know the patient in the group

Category

Treatment - Drugs

2**Description**

the control group, a drug like nasal saline was used and minutes before the infusion of the drug in the control group begins. In this way, the operator will not know the patient in the group

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ejucational @ Reserch And Medical Rajaie Center

Full name of responsible person

Dr Zahedmehr @ Maleki Farahnaz

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Dr Ali Zahedmehr

Position

cardiac Interventional Floskip

Latest degree

Subspecialist

Other areas of specialty/work

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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

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

Yes - There is a plan to make this available

Title and more details about the data/document

After completing the study, I will share the data in the article on valid seminars or journals

When the data will become available and for how long

1397

To whom data/document is available

Academic and academic institutions

Under which criteria data/document could be used

Institutions that intend to develop science and carry out new research

From where data/document is obtainable

Maleki farahnaz f.maleki@rhc.ac.ir 00989123658518

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

After contacting the mobile phone or sending an email within a week, I will send the documentation or files

Comments