Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Rajaee, Tehran, have been sampled. Blocks are used for randomization. The routine care routine questionnaire includes: Angiography, vital signs monitoring, injection of lidocaine and nitroglycerin coctails 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 pancture

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
Age
From **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 size
Target 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 Rajaee Heart Therapy Research Center Tehran
Street address
Valiasar street.Shaheed Rajaee Heart Therapy Research Center Tehran
City
Tehran
Province
Tehran
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 patientIn. 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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Valiasar street.Ejucational @ Reserch And Medical Rajaie Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 Floship
Latest degree
Subspecialist
Other areas of specialty/work

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Person responsible for updating data

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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