Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of nitroglycerine injection with placebo on angiographic complications in patients with suspected ischemic heart disease

Protocol summary

Summary

The aim of this single center phase 2 randomized controlled trial was to investigate the effects of nitroglycerine on the early complications of angiography in 123 candidates of coronary angiography. The patients were randomly assigned into intervention (111 patients) or placebo (112 patients) group to receive a mixture of dye and TNG or sterile water, respectively, for angiography. Nausea, coronary artery spasm, bradyarrhythmia, chest pain and systolic and diastolic blood pressure were measured during and after angiography and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901283733N1**
Registration date: **2010-06-12, 1389/03/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-06-12, 1389/03/22

Registrant information

Name

Masoumeh Sadeghi

Name of organization / entity

Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2005-05-10, 1384/02/20

Expected recruitment end date

2005-11-21, 1384/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of nitroglycerine injection with placebo on angiographic complications in patients with suspected ischemic heart disease

Public title

The effect of Trinitroglycerine injection on angiographic complications

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: signing informed consent, age between 20 and 75 years, no drug addiction, lack of brain vascular disease and systolic blood pressure above 100 mmHg, candidates for angiography, hemodynamic stability, Exclusion criteria: history of heart disease, history of hypertension

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size
Target sample size: **223**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan Cardiovascular Research Center/Isfahan University of Medical Sciences
Street address
Isfahan Cardiovascular Research Center, khorram Ave., Isfahan.
City
Isfahan
Postal code
81465-1148
Approval date
2005-04-20, 1384/01/31
Ethics committee reference number
84621

Health conditions studied

1

Description of health condition studied
Diseases of the circulatory system
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Nausea
Timepoint
during angiography
Method of measurement
patient observation and expression

2

Description
Coronary artery spasm
Timepoint
during angiography
Method of measurement
angiography film

3

Description
Chest pain
Timepoint
during angiography
Method of measurement
Pain by the patient during angiography is reported ECG changes in addition to rising or down piece ST

4

Description
systolic and diastolic blood pressure
Timepoint
during angiography
Method of measurement
monitoring intravascular pressure device that was attached to the patient during angiography

5

Description
Brady arrhythmia
Timepoint
during angiography
Method of measurement
ECG monitoring during angiography

Secondary outcomes

empty

Intervention groups

1

Description
Injection of 5 micrograms TNG in 150 cc Mglomyn dye. Time: During angiography.
Category
Prevention

2

Description
150 cc Myglomyn dye was mixed with 5 micrograms strile water and was injectrd during angiography.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran hospital of Isfahan

Full name of responsible person
Dr Ramin Heydari
Street address
Chamran hospital, Abshare sevom Ave., Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Director of Finance, Faculty of Medicine
Street address
Isfahan University of Medical Sciences, Azadi Square, Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Isfahan Cardiovascular Research Center/Isfahan University of medical Science
Full name of responsible person
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty