

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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

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Name of organization / entity

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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

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Isfahan Cardiovascular Research Center, Khorram Ave., Isfahan.

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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 sterile water and was injected 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

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Director of Finance, Faculty of Medicine

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Isfahan University of Medical Sciences, Azadi Square,

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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

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

Dr Masoumeh Sadeghi

Position

Associate professor of cardiology

Other areas of specialty/work**Street address**

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Web page address**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*