

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The image quality and myocardial to visceral uptake ratio in myocardial perfusion scan using pharmacological stress with sub-maximal exercise in comparison with pharmacological stress alone.

Protocol summary

Summary

Myocardial perfusion imaging (MPI) is a complex process, subject to a variety of artifacts and pitfalls, which may limit its clinical utility. Combining vasodilator and exercise stress reduces noncardiac side effects, may improve image quality, and enhance the detection of ischemia, compared with suboptimal exercise or vasodilator stress alone. However, data over combined protocols are limited. 98 patients (more than 20 years) with intermediate pretest probability of coronary artery disease referred for MPI with gated single-photon emission computed tomography (SPECT) will be studied. Regarding the type of stress before radiotracer injection, the patients will randomly allocated into two groups: one with 49 cases with dipyridamole stress alone (Dip) and the second (49 cases) with a combination of dipyridamole injection and a concomitant submaximal exercise (Dip-Exe). All patients will be imaged by 15th, 60th, 120th, 180th minutes after radiotracer injection. Region-of-interest (ROI) for different areas of the myocardium and viscera, i.e. right hepatic lobe and splenic curve of colon, will be drawn and visceral to myocardial activity will be analyzed in each patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205279881N1**
Registration date: **2012-07-04, 1391/04/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-04, 1391/04/14

Registrant information

Name

Babak Fallahi

Name of organization / entity

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University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Tehran University of Medical
Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The image quality and myocardial to visceral uptake ratio in myocardial perfusion scan using pharmacological stress with sub-maximal exercise in comparison with pharmacological stress alone.

Public title

Stress effect on myocardial perfusion scan

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: age more than 20 years; non-pregnant; non-breast feeding (for female patients); intermediate pretest probability of coronary artery disease on the basis of Framingham Risk Score and Exclusion criteria: Asthma; chronic renal failure; left bundle branch block; severe AV block; Irregularly cardiac arrhythmia; pacemaker; disability to perform submaximal exercise; congestive heart failure with EF<15%; hepatic insufficiency; cholestasis; severe aortic stenosis; patient refusal to cooperate.

Age

From **20 years** old to **149 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz boulevard, Ghods str.

City

Tehran

Postal code

Approval date

2012-05-30, 1391/03/10

Ethics committee reference number

91-01-58-9882

Health conditions studied

1

Description of health condition studied

Ischemic Heart Disease

ICD-10 code

I20

ICD-10 code description

Angina pectoris

2

Description of health condition studied

Ischemic Heart Disease

ICD-10 code

I24

ICD-10 code description

Other acute ischaemic heart diseases

3

Description of health condition studied

Ischemic Heart Disease

ICD-10 code

I25

ICD-10 code description

Chronic ischaemic heart disease

Primary outcomes

1

Description

myocardial to liver activity ratio

Timepoint

15, 60, 120 and 180 minutes after radiotracer injection

Method of measurement

Reconstruction software of SPECT

2

Description

myocardial to colon (splenic curve) activity ratio

Timepoint

15, 60, 120 and 180 minutes after radiotracer injection

Method of measurement

Reconstruction software of SPECT

Secondary outcomes

empty

Intervention groups

1

Description

Interventional group: submaximal exercise upto 3 minutes at phase 1 of Bruce protocol using treadmill in addition to conventional pharmacological stress

Category

Other

2

Description

Control group: Conventional pharmacological stress alone

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute for Nuclear Medicine, Tehran
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Full name of responsible person

Dr Babak Fallahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Tehran University of Medical
Sciences

Full name of responsible person

Dr Akbar Fotouhi

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Deputy of Research, Tehran University of Medical
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City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research, Tehran 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

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Position

Associate Professor of Nuclear Medicine

Other areas of specialty/work

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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