Persantin Preceding PCI

Published: 03-09-2007
Last updated: 08-05-2024

To test the hypothesis that dipyridamole improves tolerance to ischemia-reperfusion in patients undergoing elective PCI.

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON31171

Source
ToetsingOnline

Brief title
P3

Condition

- Coronary artery disorders

Synonym
heart infarction, ischemia-reperfusion injury

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dipyridamole, elective PCI, ischemia-reperfusion injury

Outcome measures

Primary outcome

Periprocedural troponin-I release measured 8 hours after PCI.

Secondary outcome

To study the effect of pretreatment with Persantin (retard, 2dd200mg) in

patients undergoing PCI on biomarkers reflecting atherosclerotic activity

(hs-CRP, PLA2 and PTX3) before and after pretreatment with Persantin and 8

hours after PCI.

Study description

Background summary

In elective PCI (percutaneous coronary intervention) up to 40% of the patients show an asymptomatic rise in myonecrosis marker troponin-I. This release of troponin-I has been found to represent irreversible myocardial injury and has been related to an increased risk of restenosis and even long-term mortality. Persantin has been proven to induce protection against ischemia reperfusion injury and to reduce risk of cardiovascular death or event in secondary prevention after TIA or CVA.

Study objective

To test the hypothesis that dipyridamole improves tolerance to ischemia-reperfusion in patients undergoing elective PCI.

Study design

Double-blind placebo controlled intervention study

Intervention

pretreatment with Persantin Retard, 2dd 200mg or placebo.

Study burden and risks

This study will be executed at the Radboud University Nijmegen Medical Centre under close medical supervision. Treatment with Persantin or placebo is not expected to harm the participants. We expect patients receiving Persantin will be protected against periprocedural myocardial injury.
Participants will make one extra visit to the hospital for a venepuncture and medication distribution. Participants are not allowed to drink caffeine containing beverages starting 24 hours prior to PCI and until the last bloodsampling at 8 hours after PCI.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

·Patients accepted for elective single, native vessel (left anterior descending, right coronary artery or ramus circumflexus (LAD, RCA or RCX)) PCI in the RUNMC or RUNMC cardiology

policlinic patients undergoing diagnostic coronary angiography.
·Troponin-I < 0,20 mmol/L at screening
·Informed consent

Exclusion criteria

· unstable angina
· recent myocardial infarction (STEMI or non-STEMI), during two weeks prior to inclusion
· 3-Vessel disease as seen on coronary angiogram
· Stenotic laesion in mainstem as seen on coronary angiogram
· CABG in medical history
· asthma (recurrent episodes of dyspnea and wheezing, or usage of prescribed inhalation medication: i.e. corticosteroids or B2-agonists)
· Diabetes Mellitus type I (insuline dependent)
· Use of prescribtioned oral anticoagulants (coumarine derivates)
· Use of oral corticosteroids
· Use of sulfonylurea derivates (glibenclamide, tolbutamide, gliclazide, glimepiride)
· Chronic use of Non Steroid Anti-Inflammatory Drugs (NSAID*s)
· Administration of Repro® during PCI (complicated procedure)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2007
Enrollment:	250
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Persantin
Generic name:	dipyridamole
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	03-09-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-07-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-004620-20-NL
CCMO	NL18470.091.07