Erythropoietin and coronary collateral flow in patients with coronary artery disease

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

Summary

ID

NL-OMON31082

Source
ToetsingOnline

Brief title
EPO and coronary collateral flow

Condition

- Coronary artery disorders

Synonym
angina, myocardial ischemia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Collateral formation, Coronary disease, Erythropoietin, Myocardial ischemia

Outcome measures

Primary outcome

To assess the correlation between endogenous EPO levels and coronary collateral flow

Secondary outcome

The secundary objectives are:

- to assess if there are differences in endogenous EPO leves, EPC levels and EPC function in patients with stable and unstable CAD, compared to age and sex matched controls;

- to explore the correlation between the number of functional EPCs and the extent of coronary collateral flow in patients with stable and unstable angina;

- to study the effect of resolving the coronary artery stenosis on endogenous EPO and EPC levels/function before and after the PCI procedure.

Study description

Background summary

Erythropoietin (EPO) is known to maintain a constant plasma haemoglobin (Hb) level. The main mechanism by which EPO stimulates red blood cell formation is by prevention of apoptosis of erythroid progenitor cells. Recently it has become known that EPO and its receptor are also present in other tissues like brain and myocardial tissue. Here, EPO also has an anti-apoptotic effect. Another interesting effect of EPO is the stimulation of endothelial progenitor cells (EPC)s and the subsequent growth of new vessels on existing vessels (angiogenesis). In patients with ischemia, both EPO and EPC levels are raised. These elevated levels might have a protective function for the ischemic myocardial tissue, not only by protecting myocardial cells from apoptosis, but

also by promoting coronary collateral formation. Eventually, both mechanisms will help to maintain the heart*s pumping function. To gain further insights into these mechanisms, we want to explore the relationship between EPO, EPCs and collateral growth. Therefore, we hypothesise that EPO and EPC levels are elevated in ischemic heart conditions and that a relationship exists between these levels and coronary collateral flow.

Study objective

Our primary objectives are to evaluate
- if endogenous EPO, EPC levels and EPC function are different in patients with stable and unstable CAD, compared to age and sex matched controls;
- if a correlation exists between endogenous EPO and EPC levels and coronary collateral flow in patients with both stable and unstable coronary artery disease;
- the correlation between the number of functional EPCs and the extent of coronary collateral flow in patients with stable and unstable angina;
- the effect of resolving the coronary artery stenosis on endogenous EPO and EPC levels/function before and after the PCI procedure.

Study design

This is a prospective, observational cohort study.

Study burden and risks

A standard PCI procedure will be executed by well-trained physicians and all patients will receive standard medical care. After the start of the procedure, baseline blood samples will be obtained from the introductory sheath. From 10 patients in each group, this baseline measurement will be performed by drawing blood simultaneously from the coronary sinus and from the aorta ascendens, to be able to measure the myocardial production of EPO and EPC*s. For this measurement, an additional right heart catheterisation is needed. Furthermore, in all patients, the fractional flow reserve (FFR) will be determined by injection of adenosine in the occluded coronary vessel to determine the extent of the occlusion. After the PCI procedure, the collateral flow index (CFI) will be determined for measurement of coronary collateral flow. Venous blood samples will be collected at 4 hours, 24 hours or at discharge and at 6 weeks.
From the 10 control patients, blood samples will be collected at a single timepoint.

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

Group A
• Men and women > 18 years of age
• A positive stress test or symptoms related to stable CAD
• Patients who are scheduled for an elective PCI for 1 significant stenotic lesion ;Group B:
• Men and women > 18 years of age
• Patients with an acute coronary syndrome, defined as having unstable angina with elevated troponins
• During the coarse of the PCI procedure it has become clear that a single occlusion needs to be revascularised.;Group C:
• Men and women > 18 years
• Patients who are seen at the outpatient clinic and in whom cardiac disease is excluded
• Exclusion of cardiac disease is established by laboratory tests, electrocardiogram, echocardiography and/or an exercise test.

Exclusion criteria

Group A and B:;• Previous myocardial infarction
• Previous CABG
• Signs of AMI on ECG
• Moderate renal failure (eGFR <50ml/min)
• Concomitant inflammatory or malignant disease
• Presence of other serious medical conditions
• Unwillingness to sign informed consent;group C:;• Moderate renal failure (eGFR <50ml/min)
• Concomitant inflammatory or malignant disease
• Presence of other serious medical conditions
• Unwillingness to sign informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	110
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL18735.042.07