Percutaneous coronary intervention versus conservative treatment in patients with stable angina pectoris (EUREGIO AP study): Can magnetic resonance perfusion imaging improve the triage of patients with stable angina?

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- Our primary objective is to analyze if MR perfusion imaging can guide therapy, improve patient safety and reduce costs. - The secondary objective is to determine the optimal therapy for patients with stable angina.

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

Summary

ID

NL-OMON34978

Source
ToetsingOnline

Brief title
EUREGIO-AP-study

Condition

- Coronary artery disorders

Synonym
Atherosclerosis;

Research involving

Human

Sponsors and support

Primary sponsor: Cardiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: angina pectoris, magnetic resonance, percutaneous coronary intervention, perfusion

Outcome measures

Primary outcome

The primary study parameters are a combined endpoint of time to adverse cardiac events defined as: all-cause mortality, myocardial infarction/acute coronary syndrome, hospitalization for unstable angina with negative biomarkers, coronary artery bypass grafting and coronary angioplasty.

Secondary outcome

The secondary end points are quality of life (Canadian Cardiovascular Society angina class at follow-up); the usage of antianginal drugs, cost-effectiveness and the prognostic value of hs-cTNT.

Study description

Background summary

The number of percutaneous coronary interventions (PCI*s) is rising and more hospitals wish to establish PCI-centers. However, PCI in patients with coronary artery disease is often based on morphological aspects only. The optimal therapy for patients with stable angina is under discussion: According to the COURAGE-trial, PCI as an initial treatment for stable angina did not reduce the risk of death or cardiovascular events. MR perfusion imaging has been shown to non-invasively detect myocardial perfusion abnormalities in patients with coronary artery disease and to correlate to invasive measurements of fractional

flow reserve. As the event rate in patients with normal MR perfusion results is low, we hypothesize that:
- MR imaging predicts the prognosis in patients with stable angina and guides therapy (medical treatment for minor / PCI for major ischemia),
- Triage with MR perfusion imaging can improve patient safety and reduce costs.
- Patients with major myocardial ischemia will benefit more from PCI than patients with minor or no ischemia

Study objective

- Our primary objective is to analyze if MR perfusion imaging can guide therapy, improve patient safety and reduce costs.
- The secondary objective is to determine the optimal therapy for patients with stable angina.

Study design

This is a prospective, randomized controlled study. CT angiography or coronary angiography will be performed to confirm the presence of significant coronary artery disease (>=70% stenosis). Patients will then be randomly assigned into two groups:
1) Randomization to looking at MR perfusion test results. MR perfusion imaging has been shown to correlate to invasive measurements of fractional flow reserve: a cutoff of 1.5 myocardial perfusion reserve (MPR) separates hemodynamically relevant from nonrelevant stenosis.
a. Minor ischemia (defined by visual and semi-quantitative analysis) on MR perfusion test: medical treatment.
b. Major ischemia (defined by visual and semi-quantitative analysis) on MR perfusion test: PCI in addition to medical treatment.
2) Randomization to not looking at MR perfusion test results: medical treatment.

All patients will undergo adenosine stress MR perfusion imaging.

Clinical follow-up will be performed for 5 years with yearly outpatient clinic visits and questionnaires.

Intervention

Patients with major ischemia in the *treatment with knowledge of MRI results*-group will undergo PCI according to standard technique. The cardiologist will insert a sheath into the femoral artery (or in some cases the brachial artery). A guiding catheter is pushed through this sheath and placed at the mouth of the coronary artery. Then, a small balloon on a guide wire is passed through the catheter into the coronary artery. The balloon is inflated at the location of the stenosis, which opens the blood vessel. In some cases the cardiologist will opt to use a stent on the balloon. The stent will be pressed into the arterial wall and left behind to ensure that the artery stays open.

Study burden and risks

Patients will undergo routine diagnostic work-up (i.e. physical examination, blood studies, ECG, CT angiography or coronary angiography) and one adenosine stress MR perfusion scan. Adenosine stress MR perfusion is an established method to detect myocardial ischemia and is at least non-inferior to SPECT-imaging. The use of adenosine infusion is safe and side effects are transient and generally well tolerated. Serious side effects are relatively rare, and they reverse with termination of adenosine infusion. Patients will then be treated according to their randomization:
1) Treatment with knowledge of MR results
a. Medical treatment in case of minor ischemia (defined by visual and semi-quantitative analysis).
b. PCI in addition to medical treatment in case of major ischemia (defined by visual and semi-quantitative analysis).
2) Treatment without knowledge of MR results
a. Medical treatment for all patients randomized to this group

PCI will be performed in standard technique. All patients will receive clinical follow-up for 5 years with yearly outpatient clinic visits and questionnaires.

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

All patients with stable angina pectoris and >=70% stenosis in at least one epicardial coronary artery (proximal or mid segment) can be included. Stable angina pectoris is defined as Canadian Cardiovascular Society [CCS] class I-III or medically stabilized class IV angina. Patients must be able to give informed consent.

Exclusion criteria

General:
- Age < 18 years.
- Pregnancy.
- Significant systemic hypertension (BP > 200/100mmHg) unresponsive to medical therapy.;Other cardiac pathology:
- Atrial fibrillation.
- Cardiogenic shock.
- Previous myocardial infarction, defined as: (UNL = upper normal limit)
a) New Q wave at any time.
b) Spontaneous, total CK/CK-MB >= 1.5 x UNL or troponin >= 2 x UNL.
- Congestive heart failure NYHA class >=III.
- Previous CABG or PCI.
- Unstable angina pectoris (persistent CCS class IV despite medical treatment).
- Left main (>= 50%) or 3 vessel disease or markedly positive treadmill test during stage 1 of the Bruce protocol.
- Ejection fraction < 30 %

- Concomitant valvular disease likely to require surgery or affect prognosis during follow up.
- Congenital or primary cardiac muscle disease likely to affect prognosis during follow-up.
- Resuscitated out-of-hospital sudden death or symptomatic sustained or non-sustained ventricular tachycardia.

Contraindications to MR imaging:
- Noncompatible metallic implant (vascular clip, neurostimulator, cochlear implant).
- Pacemaker or ICD.
- Claustrophobia.
- Body weight >130 kg. ;Contraindication to MRI contrastagent (Gadolinium):
- Renal failure (estimated GFR <= 30 mL/min) or chronic kidney disease stage 4 & 5.
;Contraindication to adenosine side effects:
- AV-block (2nd or 3rd degree).
- Severe asthma.
- COPD Gold IV.;To exclude patients with chest pain from non-cardiac origin, CT-angiography or coronary angiography will be performed to confirm the presence of significant coronary artery disease (>=70% stenosis).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2010
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-06-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL30607.068.09