Cross-sectional study to establish the relation between myocardial, skin and serum Advanced Glycation End-products (AGEs) levels

Published: 07-06-2010
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To establish the relation between myocardial, serum and skin AGE levels. To determine the quantitative AGE-levels in myocardial tissue

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32513

Source
ToetsingOnline

Brief title
Myocardial AGEs: a validation study

Condition

- Other condition
- Heart failures

Synonym
etiology decompensatio cordis, etiology heart failure

Health condition

patiënten die op de wachtlijst staan voor CABG en hartklep operaties

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: advanced glycation endproducts, mass-spectrometry, myocard, skin autofluorescence

Outcome measures

Primary outcome

The primary end-point of the study will be the relation between myocardial,

skin and serum AGE levels.

Secondary outcome

The secundary study parameter will be the quantitative measurement of

myocardial AGE-levels.

Study description

Background summary

Advanced glycation end product (AGE) accumulation is found throughout the body. Through formation of collagen cross-links, AGEs play a role in the pathophysiology of several different diseases. AGE accumulation has been accurately measured in tissue biopsies of the skin with gas chromatography mass spectrometry (GC-MS) but in human myocardial tissue, AGE accumulation has only been roughly measured with immunostaining. In addition, AGE accumulation in both skin and serum has never been compared to AGE accumulation in myocardial tissue. Increased AGE accumulation in skin tissue and serum have shown a correlation with decreased left ventricular systolic and diastolic function, but it has never been established if the decreased heart function is the result of increased AGE accumulation in myocardial tissue.

Study objective

To establish the relation between myocardial, serum and skin AGE levels.

To determine the quantitative AGE-levels in myocardial tissue

Study design

In this cross-sectional study we will include patiënts admissioned for CABG or heart valve surgery. Patients will be screened from the waitinglist for open heart surgery. Patients will be informed by telefone about the presence of this study. Patients will be written informed about the purpose, the study design, study duration, risks, and the consequences of preliminary ending of the study.
Patients will recieve at least one week to think about the participation to the current research. If they are willing to participate, patients will be asked to sign written informed consent.
As usual, the patients will be admissioned the day before surgery, followed by collection of blood, physical examination, non-invasive measurement of skin autofluorescence and an echocardiographic examination.
Myocardial and skin biopsies will be taken by the surgeon during the open heart surgery. The myocardial biopsies will be taken from the apex and the sternum of the left ventricle. The skin biopsie will be taken from the sternal skin allongside the surgical cutting line.
At any time during the study patients are allowed to stop their participation without any consequences. Medical care will resume normally.

Study burden and risks

Patients will be examined during their admission at hospital, which does not require an extra hospital visit. The examination will take about 30 minutes. Patients will be physically examined by the research physician and asked at the current condition, followed by colletcion of blood and measurement of the skin AGE-levels by skin autofluorescence. All these measurements, apart from the blood collection, are non-invasive and posses no additional risk.
During surgery, the surgeon will take two myocardial biopsies and one skin biopsie. This poses a limited additional risk. Myocardial biopsy is performed regularly and provides the risk of perforation and bleeding. The risks of skin biopsy include bleeding, infection and formation of scar tissue.

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

- significant coronary artery disease requiring CABG and/or severe valvular disease requiring valve surgery.

Exclusion criteria

- Fitzpatrick type V and VI skin colour
- Sustained/accepted atrial fibrillation
- Active pericarditis, endocarditis or myocarditis
- Severe myocardial fibrosis and/or hypertrophy
- history of heart transplantation

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2010
Enrollment:	10
Type:	Actual

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	NL30674.042.09