Endocrine profile of PerIcoronary adipose tissue in relation to Coronary ARtery Disease study

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To determine the relationship between pericoronary adipose tissue (dys)function, in terms of the cytokine and adipokine secretion profile and histologic markers of inflammation, and coronary atherosclerosis.

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

Summary

ID

NL-OMON36488

Source
ToetsingOnline

Brief title
EPICARD study

Condition

- Coronary artery disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Atherosclerosis, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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

Intervention

Keyword: adipocyte dysfunction, atherosclerosis, pericoronary adipose tissue

Outcome measures

Primary outcome

onderzoeksvariabelen:

- Adipokine en cytokine mRNA expression (RT-PCR) and secretion (Western blotting):

adiponectin, IL-6, TNF-α, resistin, PAI-1 en visfatin

- Histologic parameters of inflammation: macrophage infiltration (macrophages per view), capillary injection (capillaries per view) en fat necrosis (presence of) .

outcome measures:

- Stenosis (atherosclerotic plaque) measured with coronary angiography.

Secondary outcome

- Plasma adipokine and cytokine concentrations (adiponectine, IL-6, TNF-α, resistin, PAI-1 en visfatin)

- Parameters of the metabolic syndrome (waist circumference (cm), LDL-c, HDL-c, total cholesterol, fasting glucose, blood pressure)

- Adipocyte size

Study description

Background summary

Currently intra-abdominal adipose tissue is recognized as an active endocrine and paracrine organ and is associated with the development of both insulin resistance (metabolic syndrome, type 2 diabetes) and atherosclerotic vascular disease. Adipose tissue influences inflammation and hemostasis by producing pro-inflammatory cytokines (e.g. TNF-α, IL-6), adipokines (adiponectin, leptin) and other proteins (e.g. PAI-1, tissue factor)
Adipose tissue around the coronary arteries which is part of the epicardial adipose tissue (EAT) depot and produces adipocytokines and inflammatory cytokines similarly as abdominal adipose tissue, and is in close contact with the adventitia of the coronary arteries. It could be hypothesized that it stimulates the progression of atherosclerosis from *outside to inside*.

Study objective

To determine the relationship between pericoronary adipose tissue (dys)function, in terms of the cytokine and adipokine secretion profile and histologic markers of inflammation, and coronary atherosclerosis.

Study design

Cross sectional observational study.

- At the preoperative consult (>2 weeks before surgery) patients are asked if they allow the research physician to inform them about the study. The research physician will contact the patient to inform them about the study and send the written patient information and a sample of the informed consent.
- Informed consent will be signed on the day before surgery. After signing IC, medical history an physical exam will be taken.
- Blood will be drawn and coronary angiography will be performed before surgery as a part of routine clinical work up.
- during surgery an additional blood sample and adipose tissue biopsies will be taken.

Study burden and risks

Study specific side effects that could occur are minor bleeding when biopting the pericoronary adipose tissue, which will be stopped by the cardiothoracic surgeon using diathermic coagulation.

There will be no financial or health benefits for study participants, since there is no extra (time) investment because of the study.

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

Inclusion criteria
1. Written and signed informed consent.
2. Male or female patients.
3. Scheduled for elective CABG.
4. >= 50% stenosis of the RCA, LAD, diagonal branche of the LAD (DIAG) or mo branches of the RCx.

Exclusion criteria

Exclusion criteria
1. Thyroid disease (TSH < 0.35 or > 5.0 mU/L or use of thyroid hormones)

2. History of malignancy (in the last 2 years)
3. Use of thiazolidinediones
4. Use of immune suppressive medication (equivalent of prednisolon >= 10 mg /day)
5. Renal failure GFR< 30 (ml/min/1.73m2)
6. History of cardiothoracic surgery
7. History of percutaneous coronary intervention
8. coronary artery disease of more than 2 vessels

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):	03-12-2009
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO Date:	22-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-12-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-05-2011

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL28312.041.09