Observational study to investigate the regional differences in abdominal adipose tissue depots regarding function and morphology, in relation to systemic inflammation, endothelial dysfunction and atherosclerosis in patients undergoing elective abdominal aortic surgery.;korte naam: Adipose tissue Dysfunction in Patients in relation to ObeSity and vascular Events - study

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Primary Objective: To determine the differences in function and morphology of the distinct abdominal adipose tissue depots (e.g. SAT, PVAT, OAT and MAT; see figure 1) in patients undergoing elective open abdominal aortic surgery.Secondary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine and glandular disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON38295

Source
ToetsingOnline

Brief title
The ADIPOSE-II study

Condition

- Endocrine and glandular disorders NEC
- Aneurysms and artery dissections

Synonym
abdominal aortic aneurysm or localized widening (dilation) of a blood vessel

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: adipose tissue, cardiovascular disease, inflammatory markers

Outcome measures

Primary outcome

Differences in function and morphology between the distinct abdominal adipose

tissue depots, by comparing:

- The secretion profile of adipocytokines ex vivo measured with LUMINEX and

ELISA

- The mean difference in basal mRNA expression of adipocytokines of the adipose

tissues, measured by quantitative RT-PCR and

- The mean differences in morphology, measured by number and size of

adipocytes, capillaries, inflammatory cells and ischemia.

- The mean differences in number of specific inflammatory cells present in

subcutaneous versus visceral adipose tissue.

Secondary outcome

1. Mean differences in quantity of the distinct adipose tissue depots measured

from images of routinely performed CT scans, correlated to differences in functional and/or morphological parameters of the adipose tissue depots like adipocytokine secretion pattern or mean adipocyte cell size.

2. Difference between independent correlations of the different AT depots with clinical parameters of the metabolic syndrome. Therefore functional and/or morphological parameters of each adipose tissue depot (like adipocytokine secretion pattern or mean adipocyte cell size) will be correlated to clinical parameters of the patient and correlations between the distinct adipose tissue depots will be compared.

3. Mean differences in function and morphology of the distinct adipose tissue depots, correlated to systemic plasma concentrations of bioactive mediators.

Study description

Background summary

Adipose tissue is an important endocrine organ, reacting actively on nutrients and stress. The increase in wealth results in an increase in obesity, metabolic syndrome and unhealthy habits like smoking. These lead to metabolic disturbances, which is a risk factor for cardiovascular disease. Adipose tissue plays an important pathological role in cardiovascular disease, by secretion of inflammatory factors. In order to understand tha pathological pathway and subsequently develop therapeutical strategies, accurate knowledge of metabolic tissues and mechanisms is crucial. In the last decades, much research has been performed to clarify these metabolic mechanisms, and many bioactive mediators secreted by metabolically challenged adipose tissue were found to form a link between obesity and cardiovascular disease. However, many links are still missing and current known mediators have not yet been satisfying in the use for diagnostics or therapeutic purposes. Therefore it remains necessary to study the adipose tissues of humans suffering from cardiovascular disease, to unravel

the mechanisms whereby adipose tissue contributes to cardiovascular disease. From imaging studies there are indications that different adipose tissue regions in the body contribute differently to cardiovascular disease. By studying adipose tissue derived from the different regions in the abdomen, from patients suffering from severe vascular disease, we might detect differences among these regions and clues for the mechanisms by which adipose tissue contributes to vascular disease.
This research proposal focuses on the contribution of the distinct abdominal adipose tissue depots in the secretion of pathogenic mediators for vascular disease. The ability to retrieve tissues from patients undergoing abdominal surgery for an abdominal aortic aneurysm (AAA) or occlusive atherosclerosis provides the unique possibility to study the contribution of distinct adipose tissue depots to severe vascular disease.
The study population will consist of 30 male or female subjects, 18-80 years of age, referred to the UMC Utrecht for elective abdominal aortic surgery for either abdominal aortic aneurysms or atherosclerotic occlusion.

Study objective

Primary Objective:
To determine the differences in function and morphology of the distinct abdominal adipose tissue depots (e.g. SAT, PVAT, OAT and MAT; see figure 1) in patients undergoing elective open abdominal aortic surgery.

Secondary objectives
1. To determine if the differences in quantity between the distinct abdominal adipose tissue depots, measured from routinely performed CT images of patients undergoing elective open abdominal aortic surgery, can be related to differences in function and morphology between the adipose tissue depots.

2.To determine the relation between variation in function and morphology of the adipose tissue depots (SAT, PVAT, OAT or MAT) and clinical metabolic parameters like blood pressure or BMI of the patients.

3.To determine the relation between variation in function and morphology between the adipose tissue depots (SAT, PVAT, OAT or MAT) and systemic levels of adipocytokines measured in the peripheral circulation of the patients.

Study design

Observational cross sectional study

Study burden and risks

For the ADIPOSE -II study patients will be recruited that are allocated to open abdominal surgery as treatment for an abdominal aortic aneurysm or occlusive

atherosclerosis. Before surgery, patients will undergo an abdominal CT scan and a visit to the pre operative screening outward clinic which is part of their treatment.
Regarding the ADIPOSE II study, patients will be asked one blood draw, to measure biochemical values which are used for inclusion criteria as well as baseline criteria. Furthermore, patients that meet the inclusion criteria will be asked to pay one additional visit to the hospital for non invasive physical measurements and the blood draw.
Participants do not directly benefit from study participation. The scientific value, however, is considerable. After the study is ended (last participant, last measurement), participants can choose to receive an overview of some of their metabolic parameters, in order to optimise their future cardiovascular disease risk management.

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

1.Written and signed informed consent.
2.Male or female (postmenopausal) patients
3.Indicated for elective abdominal aortic surgery in the University Medical Center Utrecht

Exclusion criteria

1.Thyroid disease (TSH > 5 mU/L with clinical symptoms of hypothyroidism)
2.Hepatic disease (ASAT or ALAT > 2 times the upper limit of normal)
3.History of malignancy (in the last 2 years)
4.Use of thiazolidinediones (TZD)
5.Use of immune suppressive medication (equivalent of prednisolon >= 10 mg /day)
6.History of liposuction

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):	25-10-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	02-09-2010
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-02-2012
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	NL32757.041.10