Weightloss induced changes of adipose tissue characteristics, in relation to atrial fibrillation.

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Primary objective: to identify intra-individual changes of clinical and biochemical markers of AT characteristics before, and one year after bariatric surgery by:* Determining circulating AT derived biomarkers * Determining local AT biomarkers in...

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

Summary

ID

NL-OMON44290

Source
ToetsingOnline

Brief title
Weightloss AF

Condition

- Other condition
- Cardiac arrhythmias

Synonym
(dys)function adipose tissue, fat tissue characteristics

Health condition

eigenschappen van vetweefsel

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: VIDI grant 2013 nr 016.146.310 tnv J.R. de Groot

Intervention

Keyword: atrial fibrillation, bariatric surgery, weightloss

Outcome measures

Primary outcome

Main study parameters/endpoints

* AT mass, distribution and ratios (EAT, PAT,VAT)

* Circulating AT derived protein biomarkers, including: (1) inflammatory markers, (2) adipocytokines, (3) oxidative stress markers, (4) growth and remodelling markers, (5) markers representing AT metabolism.

* Circulating AT derived miRNAs

* Locally AT derived protein biomarkers, extracted from VAT. Markers similar to those in circulation.

* Locally AT derived miRNAs extracted from VAT.

* Anthropometric measurements: height, weight, BMI, waist-circumference, hip-waist ratio.

* Occurrence/absence of AF by an approved 7 days rhythm monitoring system.

* 1. Questionnaire about food and calorie intake: Diet journal for one week using an Internet application (Eetmeter, Stichting Voedingscentrum Nederland, The Hague, Netherlands).

* 1. EPIC Norfolk Food Frequency Intake Questionnaire

* 2. International Physical Activity Questionnaire.

Secondary outcome

Clinical data: data is gathered on the patients history and medication use and

AF associated factors such as coronary artery disease, gender, age,

hypertension, medication use and response, smoking, BMI, kidney function and

laboratory parameters.

Study description

Background summary

Obese patients experience more AF occurrences and recurrences compared to patients with a healthy BMI. Clinically, weight loss in obese patients with AF increases AF freedom in a dose-dependent manner, resulting in 50% absence of AF in patients losing >10% bodyweight. These results present a significant relationship between obesity and AF. However, details on the mechanisms underlying this relationship and on reversible pathological factors remain to be discovered.
Therefore, we designed a study in which obesity along with adipose tissue (AT) characteristics are studied upon drastic weight loss. Currently, how drastic weight loss reduces the pro-arrhythmic effect is unknown. AT characteristics before and after weight loss will be compared to AT characteristics from patients with and without AF, obtained from other studies. In this study we aim at investigating the alterations in cardiac AT mass, AT activity and anthropometrics that occur upon drastic weight loss, and at understanding how certain of these fat characteristics predispose to AF.

Study objective

Primary objective: to identify intra-individual changes of clinical and biochemical markers of AT characteristics before, and one year after bariatric surgery by:
* Determining circulating AT derived biomarkers
* Determining local AT biomarkers in visceral AT (embryological is VAT similar to EAT)
* Determining distribution, amount and ratios of local AT depots: EAT, PAT, EAT/VAT
* Determining anthropometrics: fat percentage, BMI, waist-hip ratio
* To link these characteristics (before and after weight loss) to those from

patients with and those without AF. We will use the on-going studies MARK AF (investigating defining fibrosis biomarkers in blood and atrial tissue from AF patients; NL 50069.018.14) and PREDICT AF (investigating biomarkers for fibrosis formation in blood and left atrial tissue in patients without AF; NL 50754.018.14).

Secondary objectives:
1. Determining AF presence through rhythm monitoring before surgery and during follow-up
2. To link AT activity and other AT characteristics to AF occurrence in patients from this study, before and after weight loss (in these relatively few AF patients). These two do not belong to primary objective since we assume that the AF prevalence in this cohort will not be high enough. In this non-systematically screened cohort, the AF prevalence is thought to be +/- 3%

Study design

This exploratory study will be performed in patients undergoing bariatric surgery. Patient data and material will be obtained during one visit before surgery, during surgery, at 6 months follow-up and at 12 months follow-up. Fat samples will only be extracted at baseline, while cardiac imaging, rhythm monitoring, ECG, clinical characteristics, blood samples and questionnaires will be obtained both pre-surgery and during the follow-up visits.

Study burden and risks

AF is responsible for up to one-third of ischemic strokes. AF often goes under-diagnosed in the general population, known as subclinical AF (SCAF). In comparison to controls with a healthy BMI (18,5-25), obese patients have an increased risk on developing AF. These patients may therefore extra benefit from routinely rhythm monitoring. Participation and follow-up could result in early detection of SCAF. This in turn could prevent severe, AF related complications as CVA from occurring, since proper anticoagulant treatment can be provided immediately after AF detection.
Apart from the combined regular follow up moments, patients will be asked to comply to 2 additional physician attendances. During a visit patients will undergo multiple investigations to reduce the amount of needed visitations and thereby reducing patienr burden. During these visits, 2 ultra low dose CT scans will be done (1,2 mSv each). During previous studies in the OLVG-west, extracting adipose tissue biopsies during surgery did not come with complications. A possible complication would be a bleeding, however this complication has only be described for percutaneous needle biopsies. Additionally, a potential risk comes with the ultra low CT scan, related to the radiation.

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

Patient undergoing bariatric surgery (BMI above 35)
Age above 40

Exclusion criteria

taking 2 or more antihypertensiva
taking metformine for diabetes
heart diseases, for example myocardinfarct in past

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-09-2018
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL62056.018.17