18F-FDG uptake, as marker of inflammation/metabolic activity, in vasculature and VAT and SAT.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22137

Source
NTR

Brief title
RELEASE study

Health condition

Type 2 diabetes
Obesity

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Boehringer Ingelheim

Intervention

Outcome measures

Primary outcome

• Compared associations between CVD risk factors and abdominal adipose tissue volume

• The association between abdominal adipose tissue and arterial inflammation

• 18F-FDG adipose tissue uptake differences between VAT and SAT

Secondary outcome

• The influence type 2 diabetes on 18F-FDG uptake

Study description

Background summary

Already early in the course of their disease, patients with type 2 diabetes (T2D) have considerably increased cardiovascular risk, irrespective of glycemic control. Visceral adipose tissue (VAT) is thought to play an important role, by inducing insulin resistance (IR) and non-alcoholic fatty liver disease (NAFLD) and by being metabolically active and producing adipocytokines. Its contribution to early atherosclerosis development is not fully understood. We investigated the association between VAT volume and subclinical arterial inflammation in early T2D patients by using 18F-fluordeoxyglucose (FDG) positron emission tomography (PET) with low dose computed tomography (CT) and performed a pilot to explore the value of FDG-uptake in VAT as a proxy for its metabolic activity.

Furthermore, to study whether VAT in diabetic subjects is inflamed, ex vivo 18F-FDG uptake will be determined using PET and compared with uptake in VAT and SAT.

Study objective

We hypothesize that 18F-FDG is a valide marker for metabolic activity in adipose tissue and even more pronounced in type 2 diabetes.

Study design

T0= informed consent

T1= venapuncture and 18F-FDG PET/CT scan

Intervention

Not applicable

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- Men and woman

- Age above 17 years

Exclusion criteria

- Age below 18 years

- Incompetent

- Type 1 diabetes

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Other

Start date (anticipated):	01-01-2018
Enrollment:	60
Type:	Unknown

Ethics review

Positive opinion Date:	01-10-2018
Application type:	First submission

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
NTR-new	NL7445
NTR-old	NTR7687
Other	Research register UMCG : 201700731

Study results

Summary results

1: Effect of linagliptin on pulse wave velocity in early type 2 diabetes: A randomized, double-blind, controlled 26-week trial (RELEASE). de Boer SA, Heerspink HJL, Juárez Orozco LE, van Roon AM, Kamphuisen PW, Smit AJ, Slart RHJA, Lefrandt JD, Mulder DJ. Diabetes Obes Metab. 2017 Aug;19(8):1147-1154. doi: 10.1111/dom.12925

2: Effect of Linagliptin on Arterial 18F-Fluorodeoxyglucose Positron Emission Tomography

Uptake: A Randomized Controlled Trial (RELEASE). de Boer SA, Heerspink HJ, Lefrandt JD, Hovinga-de Boer MC, van Roon AM, Juárez Orozco LE, Glaudemans AW, Kamphuisen PW, Slart RH, Mulder DJ. J Am Coll Cardiol. 2017 Feb 28;69(8):1097-1098. doi: 10.1016/j.jacc.2016.12.018