Diabetes type 2 and the role of macroalbuminuria; a diagnostic tool for vascular ageing with 18F-NaF PET/CT imaging.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22887

Source
NTR

Brief title
DETERMINE study

Health condition

Accelerated vascular ageing
Type 2 diabetes
Diabetic nephropathy/macroalbuminuria

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

To investigate whether arterial microcalcification (18F-NaF-PET detected) and macrocalcification (CT detected) are increased in patients with T2D with preserved renal function who have macroalbuminuria as compared to patients with normoalbuminuria.

Secondary outcome

1. To investigate whether arterial microcalcification (18F-NaF-PET detected) and macrocalcification (CT detected) are associated with vascular stiffness (assessed by PWV).

2. To investigate whether arterial microcalcification (18F-NaF-PET detected) and macrocalcification (CT detected) are associated with markers of the metabolic syndrome, including adipose tissue volumes (visceral and subcutaneous), adipokines, insulin resistance index (HOMA-IR), and clinical components (HbA1c, fasting glucose, lipid metabolism, and blood pressure).

3. To investigate whether arterial microcalcification (18F-NaF-PET detected) and macrocalcification (CT detected) are associated with markers of the calcium phosphate metabolism

4. To investigate which of the above mentioned factors (i.e. macroalbuminuria, metabolic syndrome, calcium phosphate metabolism, and kidney function) are independent determinants of arterial microcalcification (18F-NaF-PET detected) and macrocalcification (CT detected).

Study description

Background summary

Type 2 diabetes mellitus (T2D) is associated with a strong increase in cardiovascular risk, which is a consequence of accelerated vascular ageing. This process is hallmarked by vascular remodeling, chronic low-grade inflammation, calcification, and increased vascular stiffness. Vascular ageing is more pronounced in T2D patients who are also suffering from chronic kidney disease (CKD). But, the direct causality and mechanisms underpinning relationships between kidney function and accelerated vascular ageing is still incomplete. Macroalbuminuria could be a proxy for early changes to the vascular wall in T2D patients and therefore could be an early clinical indication of accelerated vascular ageing. Therefore, there is a clinical need to early identify those patients at risk and to explore new pathways on which new interventions can be developed.

In particular T2D patients are accompanied with obesity, and whereas visceral adipose tissue (VAT) is playing a central role in causing insulin resistance and metabolic syndrome.

To study whether vascular calcification in T2D subjects with or without macroalbuminuria is more prominent, the whole body, and therefore vasculature, will be imaged with 18F-NaF PET. With this nuclear tracer, microcalcification and therefore vascular ageing, will be imaged.
non-invasively assessed as aortic pulse wave velocity (PWV) will be performed. Also, venapuncture and a positron emission tomography (PET)/computed tomography (CT) scan will be performed with nuclear tracer 18fluor-sodiumfloride (18F-NaF).

Study objective

The hypothesis is that macroalbuminuria could be a proxy for early changes to the vascular wall in T2D patients and therefore could be an early clinical indication of accelerated vascular ageing. Therefore, there is a clinical need to early identify those patients at risk and to explore new pathways on which new interventions can be developed.

Study design

T0= informed consent

T1 = venapuncture, PWV measurement, 18F-NaF PET/CT scan

Intervention

Not applicable.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Inclusion criteria T2D patients:

• Men and women, age above 18 years

• Written informed consent

• eGFR above 60

• Fulfils ADA criteria for diabetes

o Fasting plasma glucose ≥ 7.0 mmol/l OR

o Random plasma glucose ≥ 11.1 mmol/l OR

o HbA1C ≥ 6,5%

Inclusion criteria healthy controls:

• Men and women, age above 18 years

• Written informed consent

• eGFR above 60

Exclusion criteria

Exclusion criteria T2D patients:

• Type 1 diabetes

• Clinically significant liver disease

• Other causes for macroalbuminuria than nephropathy

• Previous cardiovascular disease, defined as stable coronary artery disease or acute coronary syndrome, stroke or transient ischemic attack, peripheral artery disease

• Known atrial fibrillation

• Patients who are mentally incompetent and cannot sign a Patient Informed Consent

• Claustrophobia

• Pregnancy or breastfeeding women.

• Current active bone malignancy or in the previous 6 months

• Disorders affecting bone metabolism, e.g. hyperparathyroidism, Paget's disease

• Using vitamin K antagonists

• Using bisphosphonates, calcium or vitamin D

Exclusion criteria healthy controls:

• Type 1 or 2 diabetes

• Micro- or macroalbuminuria

• Clinically significant liver disease

• Previous cardiovascular disease, defined as stable coronary artery disease or acute coronary syndrome, stroke or transient ischemic attack, peripheral artery disease

• Known atrial fibrillation

• Patients who are mentally incompetent and cannot sign a Patient Informed Consent

• Claustrophobia

• Pregnancy or breastfeeding women.

• Current active bone malignancy or in the previous 6 months

• Disorders affecting bone metabolism, e.g. hyperparathyroidism, Paget's disease

• Using vitamin K antagonists

• Using bisphosphonates, calcium or vitamin D

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:	Pending
Start date (anticipated):	01-11-2018
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL7444
NTR-old	NTR7686
Other	Research register UMCG : 201800548

Study results

Summary results

None yet.