

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

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22887

Bron

NTR

Verkorte titel

DETERMINE study

Aandoening

Accelerated vascular ageing

Type 2 diabetes

Diabetic nephropathy/macroalbuminuria

Ondersteuning

Primaire sponsor: University Medical Center Groningen

Overige ondersteuning: Siemens

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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-sodiumfluoride (18F-NaF).

Doel van het onderzoek

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.

Onderzoeksopzet

T0= informed consent

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

Onderzoeksproduct en/of interventie

Not applicable.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 $\geq 6,5\%$

Inclusion criteria healthy controls:

- Men and women, age above 18 years
- Written informed consent
- eGFR above 60

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7444
NTR-old	NTR7686
Ander register	Research register UMCG : 201800548

Resultaten

Samenvatting resultaten

None yet.