Vascular Inflammation in Patients at Risk for Atherosclerotic Disease

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Carotid and aortic atherosclerotic plaque inflammation can be measured by [18F]DG PET/CT in humans, and is discriminative for cardiovascular risk factors

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24334

Bron
Nationaal Trial Register

Verkorte titel
VIPER

Aandoening

Cardiovascular disease
Atherosclerosis

Ondersteuning

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Overige ondersteuning: Sponsor initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Differences in TBR between groups with specific different CVD risk factors

Toelichting onderzoek

Doel van het onderzoek

Carotid and aortic atherosclerotic plaque inflammation can be measured by [18F]DG PET/CT in humans, and is discriminative for cardiovascular risk factors

Onderzoeksopzet

Single timepoint; observational study

Onderzoeksproduct en/of interventie

Observational study: single FDG-PET/CT and blood sampling.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects at risk

Patients must meet the following criteria for study entry: Patients aged equal to or greater than 50 years, Patients with an increased risk for cardiovascular disease. If using a statin, on stable therapy for at least 6 weeks prior to screening with no evidence of statin intolerance. For patients taking angiotensin-converting enzyme (ACE) inhibitors (ACE-I) or angiotensin-receptor blockers (ARBs), non-statin lipid-modifying therapy, thiazolidinediones, inhaled steroids, or leukotriene modifying agents, use of a stable dose for at least 6 weeks prior to baseline measurement. Stable Nonsteroidal anti-inflammatory drugs (NSAIDS), Cyclo-oxygenase-2 inhibitors (COXIBs) for at least 6 weeks prior to baseline measurement. Subjects are not permitted any alcohol or caffeine-containing food or drinks from 12 hrs prior to study visits until discharge. In addition, no strenuous exercise is permitted for 24 hrs before the study visits.

Healthy controls

Healthy controls must meet the following criteria for study entry: Healthy subjects aged older than 50 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects may not enter this study if they meet the following criteria: Current medical history of Auto-immune disease/vasculitis, active inflammatory diseases, proven or suspected bacterial infections. Recent (within 1 month prior to screening) or ongoing serious infection requiring IV antibiotic therapy. Use medication for diabetes mellitus, or an elevated blood pressure. Are known with a BMI above 28. Recent or current treatment with medications that may have a significant effect on plaque inflammation as measured by plaque TBR, including but not limited to: Steroids for at least 6 weeks prior to baseline measurement and during study (with the exception of inhaled steroids).
Biological based medicines (anti-TNF (ex. Infliximab), anti-IL-6 therapy (ex.

Tocilizumab) or anti-IL-1 (ex. anakinra)) within 8 weeks before the baseline visit and during the study No other Disease modifying antirheumatic drugs (DMRADS) within 6 weeks of baseline and during study (such as cyclosporine, azatioprine, etc.) Any clinically significant medical condition that could interfere with the conduct of the study. Standard contra-indications to MRI, 18FDG PET, and CT. Impaired hepatic function. Impaired renal function. Inability or unwillingness to comply with the protocol requirements, or deemed by investigator to be unfit for the study. Subject has planned cardiac surgery, PCI or carotid stenting, or major non-cardiac surgery during the course of the study period or for 14 days after the last treatment.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-11-2011
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-12-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36115
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4904
NTR-old	NTR5006
CCMO	NL37300.018.11
OMON	NL-OMON36115

Resultaten