[18F]PEG-Folate PET-CT imaging for monitoring of therapy response in Rheumatoid Arthritis patients

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[18F]PEG-Folate PET-CT imaging can show changes in quantitative tracer uptake after 4 weeks of treatment.

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

Samenvatting

ID

NL-OMON26919

Bron
NTR

Verkorte titel
Monitoring of therapy response with PET-CT imaging in RA

Aandoening

Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: GSK
Overige ondersteuning: GSK

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The tracer uptake in different joints whereby the radioactivity concentration in ROIs are

expressed as SUV.

Toelichting onderzoek

Achtergrond van het onderzoek

Rheumatoid Arthritis (RA) is a chronic systemic connective tissue disease that primarily affects the synovial joints. The inflammation is usually chronic, and may cause progressive destruction of bone and cartilage, eventually leading to loss of function. Recent international guidelines stress the importance of starting effective treatment as early as possible. A new tool for early diagnosis and therapy monitoring could greatly reduce permanent physical damage.
Positron emission tomography (PET) is a highly sensitive imaging technique that enables monitoring of disease activity and therapeutic effects. PET tracers can specifically target cells or molecules of interest. The macrophage has been shown to be a promising target for both early diagnosis and therapy monitoring, because of its infiltration in synovium from the early development of RA onwards. Studies by our research group have shown that macrophage PET imaging can visualize inflammatory activity in rheumatoid arthritis, even at subclinical levels. The potential of PET to predict therapeutic outcome of RA treatment has also been demonstrated, showing very early predictive power of PET for outcome of anti-TNF and Rituximab treatment in RA.
Recently, our group devloped a novel macrophage tracer: [18F]PEG-Folate. This binds to the β-isoform of the folate receptor, which was demonstrated to be expressed on macrophages in synovial tissue of RA patients. [18F]PEG Folate showed a excellent arthritis imaging profile in a translational approach.

Doel van het onderzoek

[18F]PEG-Folate PET-CT imaging can show changes in quantitative tracer uptake after 4 weeks of treatment.

Onderzoeksopzet

Baseline (prior to start anti-TNF treatment), 1 week, 4 weeks, 5 weeks, 12 weeks and 26 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients must be at least 30 years of age
Diagnosis of RA according to the 1987 revised criteria of the ARA13 and/or the 2019 ACR/EULAR RA classification criteria
Patients with clinically active disease as assessed by a physician; with arthritis in at least one knee or ankle joint and have a clinical indication to start with anti-TNF
Prior treatment with one anti-TNF agent is permitted, but may not be a primary failure to any anti-TNF agent
Treatment with DMARDs and oral corticosteroid up to 10mg daily is allowed, provided that there is a stable dose for at least 4 weeks prior to inclusion and during the study up to 12 weeks of follow-up
NSAIDs are permitted, provided that there is a stable dose for at least 4 weeks prior to inclusion and during the study up to 12 weeks of follow-up
Patients must be able to adhere to the study appointments and other protocol requirements
Patients must be capable of giving informed consent and the consent must have been obtained prior to the study related procedures

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Use of intramuscular or intravenous corticosteroids within 4 weeks prior to screening
Patients who received methotrexate and folic acids less than 7 days before tracer injection
Treatment with any investigational drug within the previous 3 months
Known pregnancy or breast feeding

Research related radiation exposure (cumulative ≥5 mSv) in the year before inclusion

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-09-2019
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL7920
Ander register	METC VUmc : 2019.226

Resultaten