[18F]Fluoride PET-CT imaging for detection and monitoring of bone fomration in spondyloarthritis

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[18F]Fluoride PET-CT scans visualize bone formation in spondyloarthritis patients

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

Samenvatting

ID

NL-OMON23538

Bron
Nationaal Trial Register

Verkorte titel
Fluoride PET studie

Aandoening

Ankylosing spondylitis, psoriatic arthritis

Ondersteuning

Primaire sponsor: Novartis, Foreum, Pfizer
Overige ondersteuning: Novartis, Foreum, Pfizer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Our main endpoint is [18F]Fluoride uptake changes on whole body PET-CT scans during treatment of 40 SpA patients in relation to clinical follow-up of treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

One of the hallmarks of disease activity in spondyloarthritis (SpA), a spectrum of rheumatological diseases including ankylosing spondylitis (AS) and psoriatic arthritis (PsA), is new bone formation. Enthesitis and bone formation are related to functional disability on the long term. SpA is a complex disease, as evidenced by the involvement of axial and peripheral articular structures, extra-articular manifestations, presence of co-morbidities such as osteoporosis and vascular inflammation and the histopathological combination of inflammation, tissue destruction, and new tissue formation. Mechanistic understanding of which 'targetable' pathways steer these different disease manifestations is required to optimize and tailor treatment to all these different facets of the disease.
Both TNFα and IL-17 are pivotal pathogenic cytokines in SpA. Therapeutic inhibition of each of these cytokines leads to both significant improvement of clinical symptoms and suppression of inflammation in SpA. Studies show that anti-TNF decreases inflammatory activity, and may inhibit progression of bone formation after longer use. Anti-IL-17 treatment, such as Secukinumab, has a very promising profile to inhibit not only inflammatory activity, but potentially also bone formation.
In order to investigate therapeutic effects of Secukinumab on enthesitis and related bone formation, sensitive imaging techniques are required for monitoring early in the course of treatment. Conventional X-rays and CT-scans still play an important role for determination and monitoring of structural damage, but these techniques have limitations. CT-scans do not allow assessment of the whole skeleton in one imaging session, and X-rays are more suited to provide information on long-term changes in bone formation. Both MRI and ultrasound (US) can be applied for evaluation of inflammatory activity, however US is limited to more superficial, peripheral sites that are accessible by this technique, and MRI is less sensitive for bone formation imaging in SpA.
Positron emission tomography (PET) is a promising alternative for bone formation imaging. The technique allows sensitive and quantitative imaging of functional tissue changes in the whole body by targeting specific binding sites. The visualisation of pathophysiology using specific tracers makes PET potentially suitable for early detection of disease activity, even before anatomic changes appear. In addition, it allows quantification of disease activity in order to accurately monitor therapeutic effects. Recently, our group found that disease activity of AS on PET-CT was clearly depicted with the tracer [18F]Fluoride with obvious superior targeting as compared to the reference tracers. [18F]Fluoride uptake in bone reflects local blood flow and regional osteoblastic activity because uptake takes place in the form of hydroxyapatite crystals, which form the mineral fluorapatite within the bone, especially at sites of bone remodelling. A study currently in progress of publication by our group has shown the ability of [18F]Fluoride PET-CT imaging of bone formation in AS to predict response to anti-TNF treatment.

Doel van het onderzoek

[18F]Fluoride PET-CT scans visualize bone formation in spondyloarthritis patients

Onderzoeksopzet

T0, T6, T12 and T24 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 18 years of age.
- Diagnosis of psoriatic arthritis according to the 2006 Classification Criteria for Psoriatic Arthritis (CASPAR) or ankylosing spondylitis according to the modified New York criteria
- Patients with clinically active disease as assessed by a physician;
- In PsA defined as clinically active disease with at least one clinically active enthesitis site and a clinical indication to start with Secukinumab.
- In AS defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of 4 or higher and a clinical indication to start with Secukinumab.
- Treatment with disease modifying anti-rheumatic drugs (DMARDS) and non-steroidal anti-inflammatory drugs (NSAID) is 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.
- Treatment with oral corticosteroids up to 10mg daily is 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. The anti-TNF control PsA group: prior treatment with one anti-TNF is permitted, given that the patient was intolerant for this anti-TNF (no primary failure)

- The AS biopsy group: start or treatment with either biological, NSAID and/or DMARD therapy is permitted. 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)

- Prior Treatment with anti-IL-17 (for Secukinumab starters)
- Treatment with any investigational drug within the previous 3 months.
- Pregnancy or breast-feeding

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 gestart
(Verwachte) startdatum:	15-10-2018
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	12-08-2021
Soort:	Eerste indiening

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	NL9661
Ander register	METC VUmc : 2018.001

Resultaten