

Fluoride PET-CT imaging for the detection of bone formation in (very) early and preclinical spondyloarthritis

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[18F]Fluoride PET-CT scans can detect early signs of (very) early bone formation in first degree relatives of HLA-B27 positive spondyloarthritis patients

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

Samenvatting

ID

NL-OMON25806

Bron

NTR

Verkorte titel

Pre-SpA PET

Aandoening

Spondyloarthritis

Ondersteuning

Primaire sponsor: Amsterdam UMC

Overige ondersteuning: Amsterdam UMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoints are, the number of individuals with positive lesions, the distribution of

PET-positive lesions and the quantitative [18F]Fluoride uptake in PET-positive lesions.

Toelichting onderzoek

Achtergrond van het onderzoek

A new method of visualizing new bone formation in patients with axial spondyloarthritis (AxSpA) is the use of a [18F]Fluoride Positron emission tomography (PET)-CT. It is hypothesized that in the preclinical phase of spondyloarthritis processes leading to inflammation and new bone formation are initiated. Inflammatory changes in the preclinical phase have been shown with MRI imaging. It is however unknown if new bone formation can already be observed pre-clinically.

Doel van het onderzoek

[18F]Fluoride PET-CT scans can detect early signs of (very) early bone formation in first degree relatives of HLA-B27 positive spondyloarthritis patients

Onderzoeksopzet

At T0 a whole-body [18F]Fluoride PET-CT scan will be performed. All clinical data and blood draws will be performed in the main study (Pre-SpA study).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria of the original Pre-Spa cohort:

- First-degree relatives of HLA-B27 positive AxSpA patients
- Age between 18 and 40 years at time of inclusion
- Able and willing to give written informed consent .

For this specific pilot project, we include:

- 10 participants with an MRI highly suggestive of SpA according to the ASAS definition at baseline
- 10 participants without an MRI suggestive of SpA according to the ASAS definition at baseline.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Patients already diagnosed with spondyloarthritis
- Individuals with concomitant conditions which may impact participation to the study or interpretation of the data, such as
- Individuals that have an arthritic disease other than SpA
- Individuals that have a diagnosed condition with back pain other than SpA (example: diagnosed intervertebral disc degeneration)
- Individuals with communication problems
- Individuals with psychiatric diseases
- Individuals with drug abuse
- Individuals with a life expectancy of less than five years
- Individuals who are pregnant or have a positive hcg urine test
- Individuals who are breastfeeding
- Individuals who have received treatment with any investigational drug within previous 3 months
- Individuals who already received a research related radiation burden (cumulative > 5 mSy) in the year before inclusion
- Other conditions by judgement of the physician

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	05-05-2021
Aantal proefpersonen:	20
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	NL9667
Ander register	METC AMC : 2020_167

Resultaten