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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON25806

**Source**
NTR

**Brief title**
Pre-SpA PET

**Health condition**

Spondyloarthritis

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** Amsterdam UMC

### Intervention

### Outcome measures

**Primary outcome**

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.

### Secondary outcome

Comparison of clinical features between individuals with [18F] PET positive lesion and those with negative [18F]PET-CT at baseline and follow up following the Pre-Spa Study protocol until five years after start of the study.
Evaluate if presence of [18F]Fluoride PET-lesions is related to molecular features (e.g. gene expression or serum biomarker).

## Study description

### Background summary

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.

### Study objective

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

### Study design

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).

## Contacts

**Public**
VUmc
Jerney de Jongh

020-4443981
**Scientific**
VUmc
Jerney de Jongh

020-4443981

# Eligibility criteria

## Inclusion criteria

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.

## Exclusion criteria

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

# Study design

### Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 05-05-2021 |
| Enrollment: | 20 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 12-08-2021 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL9667 |
| Other | METC AMC : 2020_167 |

# Study results