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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26919

Source
NTR

Brief title
Monitoring of therapy response with PET-CT imaging in RA

Health condition

Rheumatoid Arthritis

Sponsors and support

Primary sponsor: GSK
Source(s) of monetary or material Support: GSK

Intervention

Outcome measures

Primary outcome

The tracer uptake in different joints whereby the radioactivity concentration in ROIs are expressed as SUV.

Secondary outcome

The association between quantitative Folate PET tracer uptake in joint(s) and histological changes in synovial tissue over 4 weeks of anti-TNF treatment

Study description

Background summary

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.

Study objective

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

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

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:	Pending
Start date (anticipated):	02-09-2019
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL7920
Other	METC VUmc : 2019.226

Study results