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

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This study has been transitioned to CTIS with ID 2024-513537-21-00 check the CTIS register for the current data. To investigate the association between quantitative changes in whole body F-18-PEG Folate PET/CT (Folate PET) after 4 weeks and clinical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON52903

Source
ToetsingOnline

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

Condition

- Autoimmune disorders
- Joint disorders

Synonym
arthritis, Rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: GSK;Immune-Image Consortium

Intervention

Keyword: Imaging, PET, Rheumatoid arthritis, Therapy monitoring

Outcome measures

Primary outcome

The association between quantitative changes in Folate PET after 4 weeks of anti-TNF treatment and clinical response to therapy up to 26 weeks of treatment in patients with established RA. Clinical follow-up up to 26 weeks will be regarded as golden standard.

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 (with particular focus on macrophage infiltration, FRβ expression and macrophage polarization status).

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 diagnostic tool for early diagnostics 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 to cells or molecules of interest. The macrophage has been shown to be a promising target for both early diagnostics 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 level. 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 developed a novel macrophage tracer: [18F]PEG Folate (polyethylene glycol folate). [18F]PEG Folate binds to the β-isoform of the folate receptor (FRβ), which was demonstrated to be expressed on macrophages in synovial tissue of RA patients. [18F]PEG Folate showed an excellent arthritis imaging profile in a translational approach (in vitro, in vivo work in an animal model of arthritis and a clinical proof of concept study in RA patients). Moreover, the tracer has been synthesized as an [18F]-tracer, allowing for synthesis in a central GMP laboratory from where it can be shipped to other hospitals.

Study objective

This study has been transitioned to CTIS with ID 2024-513537-21-00 check the CTIS register for the current data.

To investigate the association between quantitative changes in whole body F-18-PEG Folate PET/CT (Folate PET) after 4 weeks and clinical response to anti-TNF therapy at 26 weeks of treatment in patients with clinically active established RA.

Study design

A multicentre, prospective cohort study in 20 clinically active, established RA patients.

Study burden and risks

The total radiation burden will be about 12.4 mSv.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Patients must be at least 30 years of age
• Diagnosis of rheumatoid arthritis according to the 1987 revised criteria of the American Rheumatism Association (ARA)13 and/or the 2010 ACR/EULAR Rheumatoid Arthritis classification criteria.
• Patients with clinically active disease as assessed by a physician; with arthritis in at least one synovial biopsy accessible joint and have a clinical indication to start or restart (if stopped >12 weeks) with anti-TNF (either Infliximab, Etanercept, Adalimumab or Certolizumab).
• Prior treatment with one anti-TNF agent (Adalimumab, Certolizumab, Etanercept, Golimumab or Infliximab) is permitted, but may not be a primary failure to any anti-TNF agent (defined as no response within the first 12 weeks of treatment)
• Treatment with disease modifying anti-rheumatic drugs (DMARDS) and oral corticosteroid up to 10 mg 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.
• 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.
• 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 acid 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 phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-08-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[18F]PEG-folate
Generic name:	[18F]PEG-folate

Ethics review

Approved WMO Date:	17-06-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-02-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EU-CTR	CTIS2024-513537-21-00
EU-CTR	CTIS2024-513537-21-02
EudraCT	EUCTR2018-004429-94-NL
CCMO	NL68286.029.19