Positron emission tomography with macrophage targeting to select individuals at risk for rheumatoid arthritis.

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This study has been transitioned to CTIS with ID 2024-513538-40-02 check the CTIS register for the current data. To determine the value of quantitative whole body PET with [18F]PEG-Folate to predict development of clinical arthritis within one year…

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

Summary

ID

NL-OMON46692

Source
ToetsingOnline

Brief title
PET for early diagnostics 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: ZonMw

Intervention

Keyword: Imaging, PET, Rheumatoid arthritis, Risk selection

Outcome measures

Primary outcome

The diagnostic performance (PPV, NPV, sensitivity and specificity) of quantitative whole body PET and macrophage targeting for development of clinical arthritis in ACPA positive arthralgia individuals during one year follow-up. Predictive ability of PET will be regarded as clinically relevant if the positive predictive value will be equal or more than 80%.

Secondary outcome

Not applicable.

Study description

Background summary

Rheumatoid arthritis (RA) is a destructive disease if not treated timely and effectively. Early and intensive treatment can limit joint damage and loss of function. The ultimate aim of early intervention is prevention of clinically active disease. A window of opportunity for very early intervention is the pre-clinical phase. To acquire rules for early treatment in this phase, risk stratification is needed. The presence of anti-citrullinated antibodies (ACPA seropositivity) in the blood and painful joints (arthralgia) are risk factors for development of clinical disease, and a prediction rule (including ACPA and arthralgia characteristics) has been developed for further risk stratification. However, a substantial portion (50-70%) of seropositive arthralgia patients did not develop RA during this time frame. For such patients treatment with associated side-effects may not be justified (at that time). Together with RA patients that participated in organised project workshops, we agreed that it is

clinically acceptable for future arthralgia patients to participate in intervention studies if a test had determined their one year risk to develop arthritis to be equal or more than 80%. Therefore, additional predictive tests are needed. Positron emission tomography (PET) and macrophage targeting might be an innovative imaging technique with promising predictive value for development of RA by non-invasive molecular imaging of the first signs of joint inflammation (arthritis). The novel characteristics of PET of specific imaging and quantification of binding sites of interest at molecular level in synovial tissue distinguishes this technique from anatomical and functional techniques as MRI and ultrasound. Our research group developed and investigated imaging of arthritis by macrophage targeting and PET in various studies in RA patients. More recently, we showed in a pilot study, that with tracer [11C]-(R)-PK11195 it is feasible to visualize arthritis activity before it becomes clinically manifest (positive predictive value of 100%). Because the imaging characteristics of the applied macrophage tracer were suboptimal to image more subtle arthritis (sensitivity of 45%), we developed a novel macrophage tracer called [18F]PEG-Folate with an improved arthritis imaging profile. A proof of concept study and dynamic study have demonstrated the potential of this tracer for the imaging of (sub)clinical arthritis.

Study objective

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To determine the value of quantitative whole body PET with [18F]PEG-Folate to predict development of clinical arthritis within one year follow-up in arthralgia patients with a positive autoantibody ACPA test.

Study design

A longitudinal, multicenter cohort PET study in 60 patients with arthralgia and an increased risk to develop RA.

Intervention

The study will involve a baseline whole body macrophage PET-CT scan follow by a clinical follow-up period of one year to assess development of clinical arthritis at 3, 6, 9 and 12 months.

Study burden and risks

The total radiation burden will be about 6.4 mSv.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients must be 18 years of age or older
2. Patients must be diagnosed with arthralgia (not secondary to trauma) by a physician
3. Patients must have a positive ACPA blood test
4. Patients must be able to adhere to the study appointments and other protocol requirements.
5. Patients must be capable of giving informed consent and the consent must have been obtained prior to the study related procedures.

Exclusion criteria

1. Arthritis and/or tenosynovitis as revealed by physical examination of 44 joints through the

Disease Activity Score (DAS) (34) by 2 independent physicians
2. Previous corticosteroid injection in joints
3. Trauma involving joints in the 6 months prior to inclusion
4. Pregnancy or breast-feeding.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2018
Enrollment:	60
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	28-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2018

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-02-2019
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	CTIS2024-513538-40-02
EudraCT	EUCTR2018-001114-15-NL
CCMO	NL65399.029.18