T cell receptor profiling in Psoriatic Arthritis.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON32436

Source
ToetsingOnline

Brief title
PAT-cell study

Condition

- Epidermal and dermal conditions

Synonym
arthritis psoriatica, psoriatic arthropathy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Farmaceutische industrie,Wyeth

Intervention

Keyword: Antigen, psoriatic arthritis, receptor, T-cell

Outcome measures

Primary outcome

Typing of pathogenic T cell population in skin an joints;

1.T-cell receptor (TCR-G) profile.

2.Gene expression profile.

Secondary outcome

1.Effects of anti-arthritic therapy on pathogenic T cells.

Study description

Background summary

Patients with psoriatic arthritis (PsA) suffer from both chronic joint and skin inflammation, resulting in a greatly reduced quality of life. Approximately 30% of patients with psoriasis will develop arthritis. However, sometimes skin signs precede arthritis and vice versa, arthritis may precede skin lesions for many years. Till today one cannot predict which patient with psoriasis will develop arthritis or not, since predictive tests are not available. It is known that the immune system and especially T cells play a major role in the pathogenesis of both arthritis and of psoriasis. However the exact phenotype and functional role of T cells that mediate inflammation in the skin and in the joints remain unclear.Treatment of PsA consists of DMARDs (disease-modifying antirheumatic drugs) that in some cases aren*t effective or whish the patient can not tolerate. In such cases treatment with biologicals is indicated .

Study objective

To investigate whether the T cell profile of T cells in inflamed skin of psoriasis patients is identical or not to inflamedskin/synovium in psoriatic arthritis patients . All this in comparison to healthy controls. By determining the clonality and the genetic profile of the T cells in inflamed tissue, a pathogenic T cell population may be identified. The results of this study will help predict which patient with psoriasis will develop arthritis and which patient not. Or which patient with arthritis will develop psoriasis and

which patient not.

Secondary objective; To investigate whether the pathogenic T-cells in inflamed joints of PsA patients are effectively reduced after standard anti-arthritic therapies.

Study design

A comparative study, whereby T cells isolated from PsA joints and psoriasis lesions will be analysed and compared with the T cell receptor profile of T cells from psoriasis skin lesions of patients without arthritis.

Study burden and risks

The results of this study could help other patients to be diagnosed in an early stage, to discriminate whether they are affected with psoriasis or psoriatic arthritis. So appropriate therapy can be given before lesions become disabling. The benefit for the patient could be an improvement or prevention of the psoriasis plaques and further joint inflammation by early treatment.
Patients will not experience higher risks when treated for PsA or psoriasis in this study, because the treatment they receive is according to current standards guidelines.
Synovial biopsies are routinely taken as a diagnostic procedure [8, 9]. Also for research purposes synovial biopsies are taken in the MEC-approved REACH study of the department of rheumatology of the Erasmus MC. Risks or complications that can occur after taking biopsies from knee or skin are possible bacterial infections, a bleeding at the location where the biopsy is taken or technical problems with the biopsy tool. There are no studies that show how big these risks are after a knee biopsy, but as a reference: an experienced rheumatologist knows that every year 1500 synovial biopsies are taken in the Netherlands and complications are rarely seen.

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

Psoriatic Arthritis group;
1.Age; 18-75 years
2.Joint inflammation of one or both knees due psoriatic artritis.
3.Patients require systemic treatment.
4.have failed to respond to, or have a contraindication for cyclosporine and other DMARDS exept MTX.;Psoriasis group;
1.Age; 18-75 years
2.Patients have psoriasis and a severity index (PASI) of 10 or more then 10 and/or Body Surface Area (BSA) of 10 or more then 10 and/or PASI of 8 or less then 8 together with skindex of 35 or more then 35.
3. Patients have psoriasis in their history for at least 10 years.
4. Patients have no signs of joint inflammation, nor in their history.
5.Patients require systemic treatment.
6.Patients have failed to respond to, or have a contraindication for cyclosporine and other DMARDS exept MTX.

Exclusion criteria

Pregnancy and lactation- active (or chronic) infections including Hepatitis B and C viral infections, HIV and tuberculosis- Malignancy in last 10 years, exept BCC and cervical insitu cancer- treatment with a biological stopped because of inefficacy, contraindication or serious adverse events, after biological therapy for minimal 12 weeks-demyelinating disease-congestive heart failure-allergies and hypersensitivities to potential anti-rheumatic drugs or their ingredients-any live virus or bacterial vaccination within 3 months- severe liver function

disorders > 2 timesand/or kidney function disorders > 1,5 times upper limits of the reference values.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	07-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL29535.078.09