Analysis of antibody production in patients with rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis.

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The goal of this stdy is to investigate both antibody responses in an invitro culture system which prevents clearance of antibodies and provides the oppertunity to study the antibodies in an antigen-free environment. This should lead to more insight...

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

Summary

ID

NL-OMON42179

Source
ToetsingOnline

Brief title
Analysis of antibody production in patients with RA, AS and PsA.

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheumatic diseases, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Reade;Jan van Breemen instituut

Intervention

Keyword: ankylosing spondylitis, antibodies, psoriatic arthritis, rheumatoid arthritis

Outcome measures

Primary outcome

- Plasma: autoantibody and anti-drug antibody characteristics, drug level,

other antibody responses related to treatment and disease, factors associated

with inflammation (e.g. TNF).

- Peripheral blood mononuclear cells (PBMCs): cell characteristics.

- PBMC culture supernatant: Antibody production, cytokine production,

production of factors associated with inflammation.

Secondary outcome

not applicable

Study description

Background summary

Patients with rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis are often treated with therapeutic antibodies. A proportion of patients develops antibodies targeting these therapeutic antibodies, resulting in loss of therapeutic effect. In rheumatoid arthritis antibodies targeting self-proteins, so called auto-antibodies, play an important role in pathogenesis and progression of disease.

Study objective

The goal of this stdy is to investigate both antibody responses in an invitro culture system which prevents clearance of antibodies and provides the

oppertunity to study the antibodies in an antigen-free environment. This should lead to more insight in development of the antibodies and more information on breath, specificity and avidity of the antibody responses.

Study design

Basis science, observational.

Study burden and risks

The additional burden consists of an extra blood sample taken at moments that this would already have been done in view of routine patient care. At each visit 18 ml blood will be collected and sent encoded to Sanquin, Amsterdam, where tests will be performed. Coded patient information will be stored in Reade. Only the medical investigator involved will have access to these data.

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

Patients with:
- rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis
- who are prescribed adalimumab, etanercept, golimumab, certolizumab pegol or abatacept by their rheumatologist
- who gave written informed consent for the study

Exclusion criteria

None.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-06-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	26-03-2015
Application type:	First submission

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
CCMO	NL50894.048.15