Lymph nodes in pre-clinical and clinical arthritis

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To investigate LN cellular composition and functional aspects of lymphnodes in pre-clinical patients eventually developing RA compared to patients that do not develop RA, and of lymphnodes of early RA patients compared to non-RA patients, all...

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

Summary

ID

NL-OMON37084

Source
ToetsingOnline

Brief title
geen

Condition

- Autoimmune disorders
- Joint disorders

Synonym
chronic joint inflammtion, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anti-CCP antibodies, lymph nodes, pathogenesis, rheumatoid arthritis

Outcome measures

Primary outcome

Differences in LN cellular composition and functional aspects of lymphnodes in pre-clinical patients eventually developing RA compared to patients that do not develop RA, and of lymphnodes of early RA patients compared to non-RA patients, all compared to lymph node tissue of healthy controls.

Secondary outcome

not applicable

Study description

Background summary

Rheumatoid arthritis (RA) is a chronic inflammatory disease mainly affecting the joints. RA is thought of as an autoimmune disease although its exact aetiology is unknown. Different inflammatory pathways have been suggested to be involved in the pathogenesis of RA. Elevation of CRP, serum cytokines, chemokines, and RA-specific antibodies precede clinical manifestations of RA. So far, no RA specific antigen has been identified. Several pathogenetic theories however, involve antigen presentation as an initiator of the inflammatory process. It is suggested that this initial inflammatory response might take place in the secondary lymphoid tissues such as lymph nodes. In animal models changes in lymph node cellular composition are observed in the latency phase of arthritis. Based on these data we think that studying lymph node cellular composition and functioning in pre-clinical and early arthritis will increase our understanding of the pathogenesis of RA if compared to lymph node tissue of healthy donors without RA-specific antibodies and without arthritis.

Study objective

To investigate LN cellular composition and functional aspects of lymphnodes in pre-clinical patients eventually developing RA compared to patients that do not

develop RA, and of lymphnodes of early RA patients compared to non-RA patients, all compared to lymph node tissue in healthy donors, in order to better understand pathogenetic processes leading to the development of clinical manifest RA and perpetuation of chronic inflammation.

Study design

Procedures:
In addition to the current pre-synoviomics and synoviomics protocol the patient will undergo histological needle biopsy of an inguinal lymph node. The lymph node will first be localised by ultrasonography and marked by the radiologist. A histological biopsy will be performed under local anaesthetics, lymph node samples will be collected and stored according to standard procedures for the analysis with different techniques.
In the follow up period this procedure will be repeated after one year, after development of arthritis, and after reaching remission defined according to the ACR criteria.
At baseline 10 ml of blood will be drawn in the arthritis patients (synoviomics) to analyse signaling molecules which might be involved in the immune activation.

The healthy controls will at baseline undergo histological needle biopsy of an inguinal lymph node (procedure as described before) and 73 ml of blood will be drawn for determining the presence of IgM-rheumatoid factor and anti-CCP antibodies and analysis of signaling molecules.
There will be no follow-up of the healthy controls.

Study burden and risks

The risk of developing a hematoma after the biopsy is about 4 %. The patient will visit our outpatient clinic several times. Total duration: 6 hours
For the healthy controls the total study duration will be 1,5 hours.

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) pre-clinical arthritis patients with positive anti-CCP or IgM rheumatoid factor OR
2) early arthritis patients with disease duration<1 year
3) healthy donors without positive anti-CCP or IgM rheumatoid factor AND without arthritis

Exclusion criteria

Present use of disease modifying anti-rheumatic drugs (DMARDs)

Study design

Design

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

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

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	NL20951.018.07