Veranderingen in het hartritme bij patiënten met reuma en bij mensen met een voorlopervorm van reuma (gekenmerkt door gewrichtsklachten en positieve reuma-antistoffen).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23052

Source
NTR

Health condition

RA
reuma
rheumatoid arthritis

Sponsors and support

Primary sponsor: AMC amsterdam
Source(s) of monetary or material Support: nvt

Intervention

Outcome measures

Primary outcome

HRV in subject with pre-clinical arthritis, patients with active RA and healthy subjects. HRV is a reflection of the autonomic nervous system and these results will be related to clinical presentation and physical examination of the subjects.

Secondary outcome

The 24-hour HRV will be analysed for day and night differences.

Study description

Background summary

Country of recruitment: The Netherlands.

Study objective

Subjects with pre-clinical arthritis will have a lower HRV compared to healthy subjects and but still a higher HRV compare to active RA-patients. Follow-up of individuals with pre-clinical arthritis will give insight in the change of HRV over time in relation to the activity and thereby progression of arthritis.

Study design

Subjects will be fitted with a Holter 24-hour electrocardiogram (ECG). Before the HRV-measurement patients will rest in supine position for approximately 20 minutes to stabilize the heart rate to get a reliable outcome.

Intervention

1. HRV will be measured in individuals with pre-clinical arthritis at three timepoints:

A. Baseline: Subjects have been found to have arthralgias and a positive ACPA and/or IgM-RF;

B. Timepoint one: At first manifestation of arthritis, characterized by pain and swelling;

C. Timepoint two: Meets ACR criteria 1987 or 5 years after baseline.

2. HRV in Patients with active RA and healthy subjects will be measured at baseline only.

Contacts

Public
Academic Medical Center (AMC), Department of Clinical Immunology and Rheumatology,
P.O. Box 22660
P.P. Tak
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171
Scientific
Academic Medical Center (AMC), Department of Clinical Immunology and Rheumatology,
P.O. Box 22660
P.P. Tak
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171

Eligibility criteria

Inclusion criteria

1. 18-85 years;

2. Individuals with pre-clinical arthritis (n=60):

A. Arthralgia and elevated ACPA level of > 25 IU/ml, or IgM-RF of > 49 IU/ml.

3. RA patients with active disease (n=20):

A. Has been diagnosed according to ACR criteria (Appendix 4: ACR -criteria);

B. Active arthritis in one or more joints at time of HRV-measurement.

4. Healthy subjects (n=20):

A. Negative for IgM-RF (level < 49 IU/ml) and ACPA (level of < 25 IU/ml).

Exclusion criteria

All subjects:

1. Cardiovascular disease, such as ischaemic heart disease, cardiomyopathy, cardiac arrhythmia, cerebrovascular events, hypertension;

2. Neurological disorders, such as parkinsonism and multiple sclerosis;

3. Diabetes Mellitus and Hypercholesterolemia;

4. Medication influencing blood pressure or heart rate;

5. Pregnancy;

6. Nicotine use (smoking , nicotinegum or patch).

Individuals with Pre-clinical Arthritis:

1. Clinically evident arthritis;

2. Use of Disease Modifying Anti-Rheumatic Drugs (DMARDs);

3. Systemic or intra-articular corticosteroid injection less then 28 days before enrolment.

Active RA patients:

1. Use of TNF-blockers or anti-IL6 treatment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011

Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion Date:	31-03-2011
Application type:	First submission

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
NTR-new	NL2304
NTR-old	NTR2833
Other	MEC AMC : 10/327
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A