

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

Gepubliceerd: 31-03-2011 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23052

Bron

Nationaal Trial Register

Aandoening

RA
reuma
rheumatoid arthritis

Ondersteuning

Primaire sponsor: AMC amsterdam

Overige ondersteuning: nvt

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Country of recruitment: The Netherlands.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 , nicotine gum 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 than 28 days before enrolment.

Active RA patients:

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	31-03-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2304
NTR-old	NTR2833
Ander register	MEC AMC : 10/327
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A