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 Laatst bijgewerkt: 18-08-2022

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...

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

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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 , 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

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