Cardiac disease in Ankylosing Spondylitis

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We hypothesize that the prevalence of cardiac disease such as valvular heart disease, conduction disturbances and decreased left ventricular function is higher in AS-patients compared with patients with osteoarthritis.

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

Samenvatting

ID

NL-OMON25008

Bron
Nationaal Trial Register

Verkorte titel
CARDAS

Aandoening

Ankylosing spondylitis, osteoartritis

Ondersteuning

Primaire sponsor: Reade
Overige ondersteuning: ReumaNederland/Reade

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Diastolic dysfunction.
Diastolic dysfunction will be defined as follows: mild diastolic dysfunction (stage I—impaired relaxation). Characterized by an E/A ratio <1, Em/Am <1, prolonged DT (>240 ms), and IVRT (>110 ms). Em (<8 cm/s) is reduced. E/Em is <10. Moderate diastolic dysfunction (stage II—

pseudo normalization). Characterized by an E/A ratio >1, Em/Am <1. Em (<8 cm/s) is reduced and E/Em is >10. Severe diastolic dysfunction (stage III— restrictive filling). This stage is characterized by an overt increased E/A ratio (>2), shortened DT (<150 ms), and IVRT (<60 ms). Em (<8 cm/s) remains at the lowest level. E/Em is >10. [13;20]

Toelichting onderzoek

Achtergrond van het onderzoek

Background - The prevalence of cardiovascular disease in patients with ankylosing spondylitis (AS) is increased and results in increased mortality. The underlying pathogenic mechanism is associated to the general inflammatory process, which causes valvular heart disease, conduction disturbances and cardiomyopathy, as well as accelerated atherosclerotic disease. Studies investigating these cardiac and atherosclerotic diseases in AS that has been performed so far are contradictory and inconclusive regarding the current prevalences of these diseases.
Hypothesis - We hypothesize that the prevalence of cardiac disease such as valvular heart disease, conduction disturbances and decreased left ventricular function is higher in AS-patients compared with patients with osteoarthritis.
Study design – Cross sectional study
Objectives - Primary objective: To investigate left ventricular diastolic function in AS-patients compared with osteoarthritis patients.
Secondary objectives: To assess the prevalence of valvular heart diseases and conduction disturbances. To assess cIMT thickness. To assess left ventricular systolic function.
Methods - Physical examinations: Anthropometry and blood pressure measurement will be performed. The standard 12-lead electrocardiogram will be recorded and cIMT will be determined as measures of prevalent cardiovascular disease. Transthoracic echography will be performed by an echo technician.
Additional assessments: CRP (marker for low-grade inflammation), triglycerides, and total, LDL and HDL-cholesterol (markers for lipid metabolism) will be determined once in a fasting blood sample. B-type natiuretic peptide will be determined as a marker of heart failure. HLA-B27 will be determined as a predictor for AS. X-rays of chest, spine and pelvis will be performed once.
Questionnaires: smoking, alcohol intake, employment, education, marital status, current medication, disease history, family history of disease, extra spinal manifestations, patient’s global assessment of disease activity (VAS), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Ankylosing Spondylitis Disease Activity Score (ASDAS), Bath Ankylosing Spondylitis Global Score (BAS-G).

Doel van het onderzoek

We hypothesize that the prevalence of cardiac disease such as valvular heart disease, conduction disturbances and decreased left ventricular function is higher in AS-patients

compared with patients with osteoarthritis.

Onderzoeksopzet

baseline

Contactpersonen

Publiek

Reade/VUmc
Milad Baniaamam

020 242 1808

Wetenschappelijk

Reade/VUmc
Milad Baniaamam

020 242 1808

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-AS according to New York (1984) criteria
-Written informed consent
-Age 50-75 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Malignant disease

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-03-2014
Aantal proefpersonen:	192
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41462
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7684
CCMO	NL44202.048.13
OMON	NL-OMON41462

Resultaten