Cardiac disease in Ankylosing Spondylitis

No registrations found.

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

Summary

ID

NL-OMON25008

Source
Nationaal Trial Register

Brief title
CARDAS

Health condition

Ankylosing spondylitis, osteoartritis

Sponsors and support

Primary sponsor: Reade
Source(s) of monetary or material Support: ReumaNederland/Reade

Intervention

Outcome measures

Primary outcome

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]

Secondary outcome

Systolic dysfunction: Systolic dysfunction will be defined as an ejection fraction of <50%.

Study description

Background summary

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).

Study objective

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

baseline

Contacts

Public
Reade/VUmc
Milad Baniaamam

020 242 1808
Scientific
Reade/VUmc
Milad Baniaamam

020 242 1808

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

-Malignant disease

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-03-2014
Enrollment:	192
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41462
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results