The impact of sex differences on cardiovascular disease in axial spondyloarthritis. From micro- to macrocirculation.

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This study aims to investigate the coronary artery system in women with axSpA by examining both morphological and functional parameters, encompassing macro- and microvascular function.

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON57330

Source
ToetsingOnline

Brief title
Burning heart

Condition

- Coronary artery disorders
- Autoimmune disorders

Synonym
axial spondyloarthritis, Bechterew disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Reumanederland

Intervention

Keyword: cardiovascular disease axial spondyloarthritis, micro-macro circulation, sex differences

Outcome measures

Primary outcome

The primary endpoints of this study are:

- CAC-score

-->Calciumscore (low, medium,high)

Secondary outcome

->Endpoints derived from CMR (morphologic and functional parameters)

->Endpoints derived from CT coronary angiography (morphologic and functional parameters)

-> Features on electrocardiogram

-> The cardiovascular risk profile:

a. Lipid profile: HDL cholesterol, LDL cholesterol, total cholesterol, triglycerides, apolipoprotein A-1 and apolipoprotein B

b. Biomarkers of inflammation, including C-reactive protein and erythrocyte sedimentation rate

c. Hemodynamic parameters: blood pressure, pulse rate.

d. SCORE2 risk prediction

Study description

Background summary

The present study proposes to estimate more accurately the cardiovascular (CV) risk and the pathophysiology of coronary artery disease (CAD) in women and men with axial spondyloarthritis (axSpA). While CV risk, beyond traditional risk factors, may differ between women and men in this patient group, it may also be higher compared to age-matched individuals in the general population. Recent studies have shown that women are more likely than men to develop coronary vasomotor/microvascular dysfunction (CMD). While the risk of developing new cardiovascular (CV) acute events, such as myocardial infarction and stroke, has been previously explored in axSpA and found to be increased, also due to higher prevalence of traditional CV risk factors, there remains a substantial gap in our understanding of the cardiac and coronary health of these patients.
Until now, there are no studies that have explored this aspect and have addressed sex differences in morphological and functional parameters of the cardiac system of individuals with axSpA by means of advanced technological modalities such as cardiac MRI and CT.
These approaches are essential because traditional cardiovascular risk factors may underestimate the risk of developing cardiovascular disease in individuals with rheumatic conditions.

Study objective

This study aims to investigate the coronary artery system in women with axSpA by examining both morphological and functional parameters, encompassing macro- and microvascular function.

Study design

A cross-sectional, descriptive study.

Study burden and risks

There are minimal risks for subjects included in this study.
Although CMR is free from ionizing radiation, participating patients will be exposed to a an effective dose of ~ 4.2 mSv due to serial CCTA imaging.
In addition, the contrast media may be nephrotoxic and elicit allergic reactions. Peripheral blood samples will be taken once, which may cause some discomfort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, patients must meet all of the following criteria:
• 18 years or older
• radiographic axial spondyloarthritis according to ASAS criteria: Assessment of Spondyloarthritis International Society (ASAS)
• HLA-B27 positive
• Able to read, write and sufficiently communicate in Dutch
• Written informed consent

Exclusion criteria

• Contraindications to CMR or CCTA (e.g. claustrophobia, ferromagnetic

implants, known allergy to iodinated or gadolinium-based contrast agents, weight or size exceeding the limits of the CMR or CCTA scanner.
• Contraindications to intravenous adenosine administration (e.g. Chronic Obstructive Pulmonary Disease stage IV or asthma, systemic hypotension with mean arterial blood pressure <70mmHg, second- or third-degree AV nodal conduction disturbances
• Known GFR < 30 ml/min
• Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	0
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-03-2025
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL87327.091.24