Detection of retinal and peripheral microvascular abnormalities in ankylosing spondylitis patients * a proof of concept study.

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Primary objective: To investigate whether AS patients have increased signs of microvascular abnormalities of the retina, compared with healthy controls.Secondary objectives: to investigate:1. the peripheral microvascular function in AS patients,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46051

Source
ToetsingOnline

Brief title
An eye for a heart

Condition

- Coronary artery disorders
- Autoimmune disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Bechterew's disease, microvascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: reumafonds en support Abbvie voor zorgvernieuwingsproject

Intervention

Keyword: ankylosing spondylitis, cardiovascular disease, peripheral microvasculature, retinal microvasculature

Outcome measures

Primary outcome

The main study parameters are the aspects of the retinal arterioles and venules, identified with SIVA (Singapore I Vessel Assessment) software of the fundus photos and the retinal thickness and vascular density on (angio) ocular coherence tomography.

Secondary outcome

The secondary parameter is the reactive hyperaemia index (RHI), measured with EndoPAT (and calculated automatically by its software). Furthermore, patient characteristics, AS disease characteristics, disease activity parameters, medication, cardiovascular risk factors and diseases, physicical exercise, profession (white or blue collar), laboratory measurements (CRP, ESR, lipid profile) and anthropometric measurements (blood pressure, BMI, arthritis, enthesitis) will be collected.

Study description

Background summary

Ankylosing spondylitis (AS) is a rheumatic disease that causes chronic

inflammation of the spinal- and sacroiliac joints and is associated with an increased risk of cardiovascular diseases. Accumulating evidence suggests a pivotal role of systemic inflammation in endothelial dysfunction, microvascular abnormalities and eventually the development of cardiovascular disease (CVD). However, in daily practice the early recognition of developing cardiovascular diseases remains a challenge. The retinal vasculature is very accessible for non-invasive visualization and provides a unique opportunity to study early structural changes of the microcirculation. The association between abnormalities of the retinal arterioles and venules and current and future cardiovascular diseases have been extensively reported. Few studies have reported on abnormalities of the retinal vasculature in chronic inflammatory diseases.

Study objective

Primary objective: To investigate whether AS patients have increased signs of microvascular abnormalities of the retina, compared with healthy controls.
Secondary objectives: to investigate:
1. the peripheral microvascular function in AS patients, measured with reactive hyperemia peripheral arterial tonometry (EndoPAT).
2. whether there is a relation between the retinal and peripheral microvascular abnormalities.
3. gender differences in microvascular abnormalities.
4. the correlation between AS disease activity and microvascular abnormalities.
5. the association between the cardiovascular risk score and retinal vascular caliber for both patients and controls.
6. differences in retinal vascular measurements between two types of fundus cameras

Study design

cross sectional case-control design in which AS patients are compared with gender- and age-matched healthy controls. Fifty-five patients and 110 controls will be included and a male-female ratio of 1:1 will be pursued. All AS patients undergo rheumatologic (short interview, physical examination, daily care questionnaires), laboratory (regular tests according to standard care), ocular assessment (inspection of the anterior eye chamber, fundus photos and a normal and angio ocular coherence tomography scan (no Röntgen radiation)) and EndoPAT assessment (specifically for this study) only once, on the same day. The ophthalmologic data of the control group was already collected for other study purposes.

Study burden and risks

The study exists of only one study visit that will approximately take 3 hours in total. No invasive diagnostics will be used. The risk and burden of the

study procedures (ocular examination and EndoPAT assessment) is considered to be negligible. The aspects that may cause (some) discomfort to the subjects are a blurred vision during 1-4 hours after ocular assessment due to mydriatic eye drops (standard procedure) and transient (maximally 5 minutes) paraesthesia of one of the hands during the EndoPAT procedure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age 50-75 years
* Diagnosis of AS according to the 1984 modified New York Criteria

Exclusion criteria

* Diagnosis of diabetes mellitus.
* History of an ischaemic stroke or cerebral haemorrhage.
* History or evidence of glaucoma, significant cataract or cataract surgery in the 6 months prior.
* Active anterior uveitis during the study visit
* Rheumatic disease other than related to AS (so: psoriatic arthritis and Inflammatory Bowel Disease are allowed)
* Current use of systemic and/or ocular corticosteroids

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2018
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO

Date:	23-08-2018
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL66784.048.18