Systemic damage and quality of life in patients with ANCA-associated vasculitis

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Primary Objectives: 1. To assess the prevalence of AAV related damage in AAV, i.e. cardiovascular damage and impaired QOL.Secondary objectives2. To assess whether there exists an association between cardiovascular disease, QOL and disease activity...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Observational invasive

Summary

ID

NL-OMON42996

Source
ToetsingOnline

Brief title
Damage in ANCA-associated vasculitis

Condition

- Mood disorders and disturbances NEC
- Nephropathies
- Vascular hypertensive disorders

Synonym
ANCA-associated vasculitis, granulomatosis with polyangitis, Wegener's disease

Research involving
Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: Foreest Medical School,Roche Nederland B.V.

Intervention

Keyword: ANCA-associated vasculitis, Cardiovascular disease, Damage, Quality of life

Outcome measures

Primary outcome

Main study parameter/endpoint

1. Prevalence of cardiovascular disease in ANCA-associated vasculitis

- Manifest cardiovascular disease: coronary artery disease, cerebrovascular disease, peripheral vascular disease, renal insufficiency, ECG abnormalities
- Subclinical cardiovascular disease: advanced glycemic end products
- Cardiovascular risk factors in ANCA-associated vasculitis: (regulated) hypertension, dyslipidemia, microalbuminuria, diabetes mellitus, renal insufficiency, smoking history
- Cardiovascular risk management

2. QOL in ANCA-associated vasculitis

- Quality of life (SF-36, EQ-5D-5L questionnaires)
- Painscore (VAS)
- Becks Depression Interventory (BDI)
- Risk factors for depression: education level, marital status, employment status, drug/alcohol abuse.

Secondary outcome

3. The association between point 1-2 and disease acitivity (BVAS, inflammation parameters, painscores, clinical manifestations). The association between point

2 and damage (i.e. VDI, painscores)

4. 5-year mortality and cardiovacular events in ANCA-associated vasculitis

patients and the association between these endpoints and classical risk factors

and disease characteristics.

Study description

Background summary

Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) is a rare disease. This necrotizing vasculitis, predominantly affects small vessels and is often associated with ANCA specific for myeloperoxidase (MPO) or proteinase 3 (PR3). Three main variants of AAV are microscopic polyangiitis (MPA), granulomatosis with polyangiitis (GPA) and eosinophilic granulomatosis with polyangiitis (EGPA). Over the last decades, survival of AAV patients has improved dramatically, but long-term sequelae from vasculitis or treatment are a major problem for most patients. Therefore quantification of this damage and the association with disease activity have become an important focus in research.

An important long-term complication of disease activity in AAV is cardiovascular disease. The current burden of cardiovascular disease in chronic AAV patients is largely unknown. Furthermore, impaired quality of life (QOL) is of high relevance to those living with chronic diseases. Thus far, only one study has addressed QOL and depression in AAV patients, showing an increased prevalence. However the prevalence of depression and impaired QOL in AAV patients in The Netherlands and the relation with disease activity have not been studied so far.

The aim of the present study is to evaluate cardiovascular damage and risk in chronic AAV patients. We will do this by measuring the burden of cardiovascular disease in AAV. Furthermore we will focus on mental health of AAV patients by assessing health related QOL, pain scores and depression scores. We will assess if these findings are related with disease activity and duration. Finally, we will perform a prospective survival analysis, in order to relate damage to survival.

The aim of this study is a better understanding of the burden of AAV related damage in chronic AAV, which will lead to a better recognition and eventually a better treatment.

Study objective

Primary Objectives:
1. To assess the prevalence of AAV related damage in AAV, i.e. cardiovascular damage and impaired QOL.

Secondary objectives
2. To assess whether there exists an association between cardiovascular disease, QOL and disease activity in AAV.
3. To investigate the association between damage and long term cardiovascular disease and survival.

Study design

We will perform a multi-center cross sectional study and a longitudinal cohort study in the Noordwest Ziekenhuisgroep, the VU University Medical Center and the Mount Sinai Hospital in Toronto. Patients with a clinical diagnosis AAV in accordance with the CHCC guidelines will be enrolled. In September 2016 patients will be sent an information letter, after which they will be contacted by the investigator for further information about the study. Permission will be asked for participation in this study.

Informed consent forms and questionnaires about QOL, depression and pain will be sent to patients home addresses. Filling out the questionnaires will take approximately 20-30 minutes. Following a routine appointment with a patients treating nephrologist, an appointment will be scheduled with the investigator. During this visit skin autofluorescence for Advanced Glycation Endproducts (AGE*s)(11) will be measured (both are described in more detail below). The vascular damage index (VDI)(9) and the Birmingham Vasculitis Activity Score (BVAS)(11) will be calculated in all patients based on interviewing the patient, physical examination and reviewing medical records. Skin autofluorescence is a non-invasive measurement for vascular damage that take a few minutes. The entire visit will take approximately 20-30 minutes. The AGE measurement will only be performed in the Noordwest Ziekenhuisgroep.

In 2016 all MPA and GPA patients will be screened routinely by an internist-nephrologist. Data of these routine visits will be withdrawn retrospectively from medical records, including: routine laboratory results, imaging results (if available), an electrocardiogram (if available) medical history and medication. Patients will be asked permission for the collection of one extra blood sample of 4 milliliters during a routine laboratory investigation within 3 months of the hospital visit with the investigator. This serum sample will be stored at -70 °C in the laboratory and will be kept for future research. This sample will only be taken during a routine venipuncture. No additional venipunctures are required. The extra blood samples will only be

After 1,2, 3, 4 and 5 years medical records will be consulted for information about prognosis, i.e. mortality, relapses,hospital admissions and cardiovascular events. If there exist any doubt on mortality or cause of death, family doctors will be contacted for further information. If a patient is still alive, he or she will be contacted by a phone call. In this phone call questions will be asked on cardiovascular events in the past year (see yearly questionnaire in the appendix). If a cardiovascular event happened outside the Noordwest Ziekenhuisgroep, permission will be asked from a patient or his/her representative (if applicable) to collect source documents, such as a hospital discharge letter.

Study burden and risks

There are no risks for included subjects in this study, since we will not intervene with routine medical treatment. The questionnaires and AGEs measurements are without risks. The patients that are enrolled in the study are unlikely to directly benefit from the study results. However future patients might benefit if chronic physicial and mental damage is better recognized and treated in an earlier stage.

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

In order to participate in this study, a subject must meet all of the following criteria:
* Diagnosis ANCA-associated vasculitis in accordance with the Chapel Hill Consensus Conference guidelines
* Age * 18 years

Exclusion criteria

Not willing or able to participate

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2016
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	31-08-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL57701.094.16