ANCA-associated Vasculitis and the Metabolic Syndrom

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This study concerns a research that is aimed to investigate the prevalence of the metabolic syndrome in a group of patients known with ANCA-associated vaculitis. Hereby we will compare the presence of the metabolic syndrome between an ANCA-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON34587

Source
ToetsingOnline

Brief title
AAV and the MetSyn

Condition

- Other condition
- Autoimmune disorders
- Vascular disorders NEC

Synonym
ANCA-associated vasculitis (inflammation of the vessel wall caused by the own immune system) and Metabolic syndrome (combination of risk factors that can lead to diseases that involve the heart or blood vessels)

Health condition

metabool syndroom

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ANCA-associated vasculitis, Metabolic Syndrome, Obesity, Wegener's Granulomatosis

Outcome measures

Primary outcome

Primary study parameter:

Is the prevalence of the metabolic syndrome (NCEP-criteria) increased within

ANCA-associated patients compared to healthy controls?

Secondary outcome

Secundary study parameters:

- Do relapses occur more frequently within ANCA-associated vasculitis patients

who meet the criteria for the metabolic syndrome compared to ANCA-associated

vasculitis patients without the metabolic syndrome?

- Are the ANCA levels persistently higher within ANCA-associated vasculitis

patients who meet the criteria for the metabolic syndrome?

- Is the C-reactive protein (CRP) persistently higher within ANCA-associated

vasculitis patients who meet the criteria for the metabolic syndrome?

- Does proteinuria occur more often within ANCA-associated vasculitis patients

who meet the criteria for the metabolic syndrome?

Study description

Background summary

Atherosclerosis and vasculitis are systemic inflammatory diseases (1). Immune processes caused by activity of T cells and antibodies play an important role in this matter (1,2).
A high incidence of clinical manifestations of vascular disease like premature atherosclerosis, has been demonstrated in patients with auto-immune diseases like systemic lupus erythematosus (SLE), rheumatoid arthritis en ANCA-associated vasculitis (AAV) (1). Cardiovascular diseases are a major cause of mortality in patients with small vessel vasculitis. (1). During an active period of disease, these patient experience an acceleration of the atherosclerotic process (1). Important risk factors like diabetes mellitus, hypertension, impaired renal function, persistent proteinuria and increased levels of C-reactive protein (CRP) are more often present within this patient group compared to healthy controls (1). Nevertheless, there is still much unknown about the pathophysiology of accelerated atherosclerosis in these patients (1), mainly regarding its relationship to the development of the metabolic syndrome.

The incidence and prevalence of the metabolic syndrome is very high in The Netherlands and worldwide (3,4). In the Hoorn Study a prevalence of 17 tot 32% was found (3). In another Dutch study which combined the results of the studies 'PREVEND' and 'MORGEN' a prevalence of 14% was measured (4). There are clear indications that immune processes are involved in the pathophysiology of the metabolic syndrome (5). To our knowledge, studies of the relation between the metabolic syndrome and ANCA associated vasculitis have never been reported until now.

In the current study proposal the presence of the metabolic syndrome will be investigated in as ANCA-associated patient cohort group. The main focus lies within the possibly disturbed immune regulation as the underlying mechanism of the development of the metabolic syndrome. The study will be performed in a known ANCA-associated vasculitis patient group at the MUMC. Partners of the patients will be approached and asked to take part of the study as healthy controls.

The occurrence of the metabolic syndrome within ANCA-associated vasculitis patient and healthy controls will be studied in a cross-sectional study design. Parameters for inflammation will be analyzed and correlated to the

presence of the metabolic syndrome within the ANCA-associated vasculitis group.

Study objective

This study concerns a research that is aimed to investigate the prevalence of the metabolic syndrome in a group of patients known with ANCA-associated vaculitis. Hereby we will compare the presence of the metabolic syndrome between an ANCA-associated vasculitis cohort group and a group of healthy controls .
There are indications that immune processes are the underlying conditions needed for the pathophysiology of the metabolic syndrome; on the other hand we postulate that the presence or absence of the metabolic syndrome, can influence the course of the vasculitis. Throught this study we want to have more insights over this relationship.

Study design

This study concerns a cross-sectional study that will be performed in the course of 1 year at the MUMC.
The research can be divided into 3 steps:

1) Inclusion of patients and healthy controls:
- measurement of blood pressure + abdominal circumference + weight + length
- measurement of blood fasting-levels of glucose, triglycerides, cholesterol
- questions about smoking history and medical history.

2) Included patients:
- look up measurement of albumin levels in urine + CRP + neopterine + relapses + ANCA (en subtypes) in the patient files.

3) Included healthy controls:
- measurement of blood pressure + abdominal circumference + weight + length
- measurement of blood fasting-levels of glucose, triglycerides, cholesterol
- questions about smoking history and medical history.

Study burden and risks

Patients and healthy controls will be examined during outpatient controls where their blood pressure, weight, length and abdominal circumference will be measured. Within the patient group, the fasting-state blood levels that may indicate the presence or absence of the metabolic syndrome (cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, glucose) and parameters that indicate disease activity (CRP, PR3-ANCA, MPO- ANCA, neopterine) will be determined during the regularly taken bloodtests. Furthermore, healthy controls will be examined as well via a sole blood test regarding the parameters that may indicate the presence or absence of the metabolic syndrome as mentioned

above.

The possible adverse events for patients and healthy controls in this study are limited to the eventual development of a hematoma after venipuncture. This requires no further interventions.

Our experience is that patients and their partners are very approachable with regard to research. In our opinion a sole blood test for the healthy controls is a reasonable strain. Considering the small amount of strain asked form both the patients and the healthy controls, and the advantage of gaining more knowledge about the relationship between ANCA associated vasculitis and the metabolic syndrome, we regard the execution of this research as justifiable.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
- Age: > 18 years
- Diagnosis: ANCA-associated vasculitis according to the classification criteria of Watts et al.
- Known with the disease for more than 1 year.;Healthy controles:
- Partner of included patient.

Exclusion criteria

Patients:
- Patients do not fulfil the classification criteria of Watts et al.
- Under aged and legally incapable.
- Immunosuppressive medication: > 15 mg prednison;Healthy controles:
- Under aged and legally incapable

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	25-11-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL33199.068.10