Researching trained immunity in ANCA-associated vasculitis

Published: 26-06-2023
Last updated: 30-11-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON53213

Source
ToetsingOnline

Brief title
TACTIC-AAV

Condition

- Autoimmune disorders
- Vascular disorders NEC

Synonym
AAV, ANCA-associated vasculitis, Wegner

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AAV, innate immune cells, trained immunity

Outcome measures

Primary outcome

1. What are the differences in the transcriptome of circulating monocytes from AAV patients when the disease is in remission or when the disease is active (flares), and how does this differ with the transcriptome of circulating monocytes from healthy individuals?

2. What are the differences in the epigenome of circulating monocytes from AAV patients when the disease is in remission or when the disease is active (flares), and how does this differ with the epigenome of circulating monocytes from healthy individuals?

3. What are the differences in the cytokine response of circulating monocytes from AAV patients when the disease is in remission or when the disease is active (flares), and how does this differ with the response of circulating monocytes from healthy individuals?

Secondary outcome

1. Are there correlations between the trained immunity profile of circulating monocytes (identified by transcriptome, epigenetics, and cytokine response) and the degree of current disease activity in clinical variables of AAV patients?

2. Are there correlations between the trained immunity profile of circulating

monocytes (identified on the basis of the transcriptome, epigenetics, and cytokine response) and the risk of the occurrence of flares in the future.

3. Are there correlations between the trained immunity profile of circulating monocytes (identified based on the transcriptome, epigenetics, and cytokine response) and inflammatory markers in the blood.

Study description

Background summary

ANCA vasculitis is an autoimmune disease in which small- to medium-sized blood vessels are inflamed and anti-neutrophil cytoplasmic antibodies (ANCAs) are detectable in the serum. ANCA vasculitis can produce a size variety of symptoms and several organs may be affected, including the lungs, skin and kidneys. Organ damage, including kidney failure, may result. Dialysis or a kidney transplant are then the only options for patients.

In ANCA vasculitis, ANCAs in the serum activate neutrophils of the innate immune system by binding to MPO/PR3 on these neutrophils. However, how the production of ANCAs comes about and what role other cells of the innate immune system, such as monocytes and macrophages, play in ANCA vasculitis is still largely unclear.

In this study, we are investigating trained immunity in ANCA vasculitis patients. Trained immunity is a form of memory of innate immune cells, which causes higher inflammatory activity upon stimulation. Our hypothesis is that trained immunity may lead to activation of the immune response in ANCA vasculitis patients and contribute to disease flare.

Study objective

In this study, we therefore aim to investigate how trained immunity is systemically regulated in ANCA vasculitis patients and how the degree of trained immunity affects disease activity and severity. A better understanding of these processes contributes to the discovery of new targets for therapy for ANCA vasculitis patients.

Study design

This is a clinical observational study.

Study burden and risks

This is an observational study in which participants complete a questionnaire, have their blood pressure measured and donate body fluids (urine and blood), In our view, there are no risks associated with this. The burden for participation in this study is minimal and consists of a 1-hour visit to our outpatient clinic.

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 between 18 and 70 years old.
Positive AAV diagnosis.

Exclusion criteria

Lack of informed consent
Current infection
CKD stage 5 or dialysis
Pregnancy
Active cancer

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-06-2024
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	26-06-2023
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	NL84182.091.23