

# Probiotics in atherosclerosis: a pilot study

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The objective of the study is to see whether oral administration of probiotics can modulate certain immunological markers which are associated with accelerated atherosclerosis in patients with ANCA associated vasculitis.

|                              |                      |
|------------------------------|----------------------|
| <b>Ethical review</b>        | Approved WMO         |
| <b>Status</b>                | Recruitment stopped  |
| <b>Health condition type</b> | Autoimmune disorders |
| <b>Study type</b>            | Interventional       |

## Summary

### ID

NL-OMON30643

### Source

ToetsingOnline

### Brief title

Probiotics in atherosclerosis

### Condition

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

### Synonym

atherosclerosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Ziekenhuis Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W, fonds voor het hart; dit is een onafhankelijke stichting die subsidies verleent ten bate van onderzoek naar het voorkomen van hart en vaatziekten

## Intervention

**Keyword:** atherosclerosis, HSP-60, probiotics, vasculitis

## Outcome measures

### Primary outcome

- phenotype of the CD4+/CD28- T-cells
- measurement of other lymphocyte subsets (NK cells en regulatory T-cells)

these cells will be tested on specificity for HSP-60 antigen

- quantitative measurement of circulating HSP-60 en HSP-60 antibodies
- quantitative measurement of circulating interleukin 10
- selected CD4+/CD28- T-cells stimulation tests with measurement of IL-10

production and intracellular cytokins

### Secondary outcome

not applicable

## Study description

### Background summary

Cerebrovascular accidents en myocardial infarction are complications of atherosclerosis. Atherosclerosis is a chronic vascular disease in which inflammation is an important factor. The etiology of this inflammation is not yet illucidated. Research however showed that humoral immunological mechanisms may play a pivotal role. Antibodies against oxidated LDL and heat shock protein 60 (HSP-60) seem to be the most relevant. Also antigen specific T-cells have been isolated from atherosclerotic plaques. Anti neutrophil cytoplasmatic antibodies (ANCA) associated vasculitis is a chronic inflammatory vessel disease. Patients with ANCA associated vasculitis seem to have an increased risk for cardiovascular complications. HSP-60 antibodies and a increase in CD 4+ / CD28- T-cell counts are associated with this increase in risk. Research demonstrated that these T-cells are antigen specific to HSP-60. Certain probiotic are able to decrease interferon gamma (atherogenic) levels in plasma and to increase interleukin 10 ( anti atherogenic). Furthermore probiotics

which produce HSP-60 may induce tolerance for HSP-60.

## **Study objective**

The objective of the study is to see whether oral administration of probiotics can modulate certain immunological markers which are associated with accelerated atherosclerosis in patients with ANCA associated vasculitis.

## **Study design**

In this pilot study ten patients will be selected with a proven ANCA associated vasculitis and increased CD4+/CD28- T-cell count. There will be a period of 16 weeks follow up. The first four weeks patients will be administered either a placebo or pro-biotics, hereafter there will be a four week lasting period of wash-out. The last four weeks patients will crossover to probiotics or placebo. At week 0, 4, 8, 12 and 16 blood will be drawn for immunological essays (see below). Patients will be asked to fill out a questionnaire to evaluate the compliance.

## **Intervention**

The intervention will be administration of probiotics. Immunological parameters before and after administration will be compared.

## **Study burden and risks**

Extent of burden:

- 5 times visit to outpatient clinic
- 5 times a blood test
- to fill out a questionnaire
- to bring the used sachets to the outpatient clinic

## **Contacts**

### **Public**

Academisch Ziekenhuis Maastricht

P Debijelaan 25  
6202 AZ Maastricht  
Nederland

### **Scientific**

Academisch Ziekenhuis Maastricht

P Debijelaan 25

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

patients with ANCA associated vasculitis  
increased CD4+/CD28- T-cell counts

### Exclusion criteria

No significant immunosuppressive therapy

## Study design

### Design

|                     |                         |
|---------------------|-------------------------|
| Study phase:        | 2                       |
| Study type:         | Interventional          |
| Intervention model: | Crossover               |
| Masking:            | Open (masking not used) |
| Control:            | Uncontrolled            |
| Primary purpose:    | Treatment               |

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 15-10-2007  
Enrollment: 10  
Type: Actual

## Ethics review

Approved WMO  
Date: 08-08-2007  
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     | NL12434.068.06 |