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 accelarated atherosclerosis in patients with ANCA associated vasculitis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	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

- quantitive measurement of circulating HSP-60 en HSP-60 antibodies

- quantitive measurement of circulating interleuking 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 immunlogical 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 asssociated 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 accelarated 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 questionaire te evaluate the compliance.

Intervention

The intervention will be administration of probiotics. Imunnological 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 questionaire
- to bring the used sachets to the 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

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

Exclusion criteria

No significant immunosupressive 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