Feasibility study to use new techniques/biomarkers to measure oxidative stress and the influence of vitamin E&C on these parameters in patienst suffering from intermittent claudication.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28549

Source
NTR

Brief title
0112 X

Health condition

Patients suffering from intermittent claudication are followed during exercise on a standard treadmill. Experiments are repeated after antioxidant suppletion (vitamins E & C).

Sponsors and support

Primary sponsor: Unilever Research, Vlaardingen
Maxima Medical Center, Eindhoven/Veldhoven

Intervention

Outcome measures

Primary outcome

Levels of 'new' parameters of oxidative stress like isofuranes and halogenated phospholipids are determined. Also vascular parameters (fibrinogen, PAI-1 activity etc) and endothelial damage parameters (soluble thrombomodulin, von Willebrand factor etc) are determined. New techniques like multivariate NMR will be determined for their usefulness in the above mentioned type of studies.

Secondary outcome

N/A

Study description

Background summary

The feasibility to use new techniques like multivariate NMR in studies on oxidative stress in vascular diseases is determined. Patients suffering from claudication intermittens are followed during exercise on a standard treadmill. Under these conditions the patients are exposed to an increased level of oxidative stress. Levels of 'new' biomarkers for oxidative stress are compared with levels of more traditional biomarkers for this condition. New techniques like multivariate NMR are examined for their usefulness in the above mentioned type of studies.

Study objective

Multivariate Nuclear Magnetic Resonance (NMR) can be used to measure oxidative stress in patients suffering from intermittent claudication.

Study design

N/A

Intervention

Patients will receive antioxidant supplementation with high concentrations of vitamin E (200 mg/day) and vitamin C (1000 mg/day) during 4 weeks.

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Eligibility criteria

Inclusion criteria

Stable (more than 6 months regarding subjective walking distance) patients with claudication intermittens.

Exclusion criteria

Patients with pre-existing renal dysfunction and those not able to perform a standard walking test.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2002
Enrollment:	13
Type:	Actual

Ethics review

Positive opinion

Date:	10-10-2005
Application type:	First submission

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
NTR-new	NL353
NTR-old	NTR392
Other	: METC 0114 / 0112 X
ISRCTN	ISRCTN69086952

Study results

Summary results

NMR Biomed. 2008 Feb 1. [Epub ahead of print]