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

Submission date 23/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/02/2007	**Overall study status** Completed	
Last Edited 26/03/2021	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
METC 0114/0112 X, NL353 (NTR392)

Study information

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

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received by the Medical Ethical Review Board of Máxima Medical Centre in Eindhoven /Veldhoven on October 2, 2001 (ref: METC 0114).

Study design
Crossover feasability study

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Intermittent claudication

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

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Antioxidant supplementation with high levels of vitamin E and vitamin C

Primary outcome measure
Levels of 'new' parameters of oxidative stress like isofuranes and halogenated phospholipids are determined. Also vascular parameters (fibrinogen, Plasminogen Activator Inhibitor-1 [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 measures
No secondary outcome measures

Overall study start date
01/01/2002

Completion date
01/04/2004

Eligibility

Key inclusion criteria
Stable (more than six months regarding subjective walking distance) patients with intermittent claudication.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
13

Total final enrolment
17

Key exclusion criteria
1. Patients with pre-existing renal dysfunction
2. Those not able to perform a standard walking test

Date of first enrolment
01/01/2002

Date of final enrolment
01/04/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
P.O. Box 7777
Veldhoven
Netherlands
5500 MB

Sponsor information

Organisation
Máxima Medical Centre (The Netherlands)

Sponsor details
P.O. Box 7777
Veldhoven
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5500 MB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02x6rcb77

Funder(s)

Funder type
Industry

Funder Name
Máxima Medical Centre (The Netherlands)

Funder Name
Unilever Research Vlaardingen, Unilever Health Institute (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2008	26/03/2021	Yes	No