

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
Registration date 23/02/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/03/2021	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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).

Primary study design

Interventional

Study design

Crossover feasibility study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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**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