Evaluation of reactive hyperemia and ischemia-reperfusion using the EndoPAT

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The objectives are to explore in a step-wise approach the possibility to study reactive hyperemia and ischemia-reperfusion phenomena in humans by simultaneous assessment of vaso-reactivity and autonomous nervous system function.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vascular injuries
Study type	Observational non invasive

Summary

ID

NL-OMON33369

Source
ToetsingOnline

Brief title
Evaluation of endothelial function

Condition

- Vascular injuries

Synonym
Endothelial function

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: CHDR

Intervention

Keyword: EndoPAT, Endothelial function, Ischemia reperfusion, non-invasive

Outcome measures

Primary outcome

Heart rate variability, the augmentation index and hyperemia index.

Secondary outcome

na

Study description

Background summary

Normal functions of endothelial cells include mediation of coagulation, platelet adhesion, immune function, and control of volume and electrolyte content of the intravascular and extravascular spaces. In case of endothelial dysfunction, the normal biochemical processes carried out by the endothelium are disturbed. Endothelial dysfunction can result from disease processes, as occurring in hypercholesterolemia, septic shock, hypertension, and diabetes, as well as from environmental factors, such as smoking. Endothelial dysfunction is thought to be a key event in the development of atherosclerosis, and has also been shown to be of prognostic significance in predicting vascular events including stroke and heart attacks1. Endothelial function has been shown to be impaired in patients with coronary artery disease (symptomatic and asymptomatic), type II diabetes mellitus, hypertension, obesity, and hypercholesterolemia 2-9. Importantly, several prominent researchers state that endothelial dysfunction might be the causal pathological mechanism behind metabolic diseases (*common soil hypothesis*).
Endothelial function can be measured using non-invasive and invasive techniques. CHDR has recently acquired a device that allows non-invasive measurement of vaso-reactivity: the EndoPAT (Peripheral Arterial Tone). The main applications of this device are the measurement of the arterial pulse wave at a finger artery during rest and after occlusion of the blood flow in the arm (reactive hyperemia) and to estimate arterial stiffness (augmentation index). However, it is reasonable to assume that the device can also be used to study ischemia-reperfusion (I/R) phenomena by increasing the duration of the occlusion. Therefore a study is proposed to investigate whether read-outs of the device after prolonged arterial occlusions may be suitable parameters to be used as biomarkers for I/R-injury. As at present the experience with the device

is limited, the development of the I/R model will be preceded by a series of experiments to document the performance of the device, as described in this protocol. This includes experiments on intra- and inter-individual variability, diurnal variability, and age and gender differences. Also the influence of known modulators of endothelial function (smoking, food and xanthine intake, etc.) will potentially be addressed.
As it is likely that the experiments will be influenced by the tone of the autonomic nervous system, recording of heart rate variability will be done simultaneously. Previously, CHDR used another non-invasive device (Finapres) to record the arterial pulse wave. This device will also be used in the proposed experiments.

Study objective

The objectives are to explore in a step-wise approach the possibility to study reactive hyperemia and ischemia-reperfusion phenomena in humans by simultaneous assessment of vaso-reactivity and autonomous nervous system function.

Study design

The study will be carried out as an open, observational study.

Study burden and risks

na

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

Be at least 18 years of age;
Able to keep to the diet and other restrictions and instructions as listed in the protocol.
Able and willing to sign the Informed consent form.

Exclusion criteria

In general: any clinically significant disorder (current or past medical history or physical examination) that in the opinion of the investigator precludes study participation.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-03-2009

Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	15-06-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL27056.058.09