Investigating the influence of the cold pressor test on cerebral blood flow regulation

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

Summary

ID

NL-OMON42979

Source
ToetsingOnline

Brief title
Cerebral blood flow

Condition

- Other condition

Synonym
cerebrovascular disease

Health condition

hersenaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Geriatrie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: perfusion, sympathetic nervous system, vascular health

Outcome measures

Primary outcome

Cerebrovascular perfusion is examined at the level of the middle cerebral artery using TransCrandial Doppler (TCD, in cm/s) and cerebral cortex using near infrared spectroscopy (NIRS; concentration oxy/deoxy Hb in mmol/L). Furthermore, common carotid artery blood flow is measured with ultrasound (cm/s). These measurements will be performed before and across a 3-minute period of the CPT.

Secondary outcome

Secundary parameters are ECG (3 lead), blood pressure (Finapres), and end-tidal CO2.

Study description

Background summary

Atherosclerosis is the pathophysiological process underlying cardiovascular disease. Early detection of cardiovascular risk is possible by identifying individuals with endothelial dysfunction. Recent work explored the ability to examine endothelial function by examining carotid artery responses to sympathetic stimulation using the cold pressor test. To understand the mechanisms behind blood flow and diameter responses to sympathetic stimulation, it is important to examine these blood flow responses across several levels of the cerebrovascular tree.

Study objective

The primary aim is to characterize the cerebrovascular and common carotid artery blood flow response to the cold pressor test (CPT). The secondary objective is to explore to potential differences in these cerebrovascular and carotid artery responses between young and older humans.

Study design

Observational study

Study burden and risks

Participation will cost only one visit of approximately one hour. The techniques used (TCD, NIRS, US) have no risk for the participants. The CPT may cause mild discomfort, which is quickly alleviated after the 3 minute time frame and does not result in any lasting effects. Healthy elderly participants are preferred, because age is an important confounder for the outcome of these imaging techniques, while at the same time, the highest prevalence and therefore clinical relevance of cardiovascular and cerebrovascular disease is observed in this age group.

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

* Young adult group: aged 18-30 years
* Elderly group: aged *65 years
* Normal cognition, determined by MoCA Score * 26
* Able to provide informed consent

Exclusion criteria

* Diagnosis of significant neurological or psychiatric diseases relevant for brain function or (cerebral) blood flow (e.g. stroke, dementias)
* History of brain surgery
* Diabetes mellitus, cardiovascular disease, hypertension, epilepsy
* Carotid artery stent or severe stenosis

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	15-05-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL60319.091.16