Near-infrared spectroscopy during lower body negative pressure

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33113

Source
ToetsingOnline

Brief title
NIRS during LBNP

Condition

- Other condition

Synonym
Hypovolemia

Health condition

Hemorrhagic shock

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Hutchinson Technology Inc., Hutchinson, Minnesota, USA,Hutchinson Technology Inc.;Hutchinson;Minnesota;USA

Intervention

Keyword: Hypovolemia, LBNP, NIRS, Oxygen saturation

Outcome measures

Primary outcome

Hemodynamic measurements

Heart rate, beat-by-beat SBP, diastolic blood pressure, and stroke volume will be measured non-invasively using an infrared finger photoplethysmograph (Finometer Blood Pressure Monitor, TNO-TPD Biomedical Instrumentation, Amsterdam, The Netherlands) and a bio-impedance measurement system (Cheetah BioImpedance Cardiography). The Finometer blood pressure cuff will be placed on the middle finger of the left hand which, in turn, will be laid at heart level.
Mean arterial pressure will be calculated by dividing the sum of SBP and twice diastolic blood pressure by 3.

Non-invasive measurement of forearm and thenar oxygen saturation

All patients will be tested with one multi-depth InSpectra device on the forearm and one multi-depth InSpectra device on the thenar, simultaneously.
StO2 will be continuously and non-invasively measured using two InSpectra

Tissue Spectrometers (Multi-depth Model, Hutchinson Technology Inc., Hutchinson, MN), which use reflectance mode probes which have one 1.5 mm optical fiber to illuminate the tissue and 3 optical fibers to detect the backscattered light from the tissue. The spatial separation between the illumination fiber and the 3 detection fibers will be 2.5, 15, and 25 mm. The relative optical attenuation of the backscattered light at four wavelengths (680, 720, 760, and 800 nm) is measured to calculate two second-derivative attenuation values, one centered at 720 nm, and the other at 760 nm. A ratio of the 720 nm to 760 nm second derivative values is directly related to StO2, defined as [HbO2]/[Hb]+[HbO2], via a calibration table. The calibration table relating StO2 to the second derivative attenuation ratio is stored permanently within the monitor and common to each monitor and probe used. The NIRS devices were calibrated before the first measurement in each subject using a light-scatter calibrator.
The devices are both equipped with two temperature sensors: one for core temperature measured in the ear and one for skin temperature measured at the site of the NIRS probe.

Vascular occlusion test (VOT)

One multi-depth NIRS probe will be placed on the skin of the right thenar eminence and another multi-depth NIRS probe will be placed on the lateral side of the anterior surface of the right forearm for simultaneous measurement of thenar and forearm StO2 during the VOTs. Both hand and forearm will be kept at

heart level with the palms up and the subjects will be instructed not to move their hand or arm during measurements. The VOTs will be performed before the application of LBNP, at -40 mmHg, and at the end of the experiments (LBNP = 0 mmHg).

After a 3 min stabilization period (baseline measurement), stagnant ischemia will be induced for 3 min by rapidly inflating a pneumatic cuff (i.e., <5 sec), placed around the right upperarm, to 50 mmHg above SBP. Subsequently, the cuff will be deflated (i.e., <1 sec) and StO2 measurements continue up to 5 min post-ischemia.

Secondary outcome

n.v.t

Study description

Background summary

Early diagnosis of blood loss is a high priority for treatment of circulatory shock since hemorrhage is a leading cause of death in civilian and military trauma. Unfortunately, compensatory mechanisms that buffer against changes in regulated variables, such as blood pressure and arterial oxygen saturation, make standard physiologic measurements poor indicators for early assessment of shock. Standard examinations of mental status, pulse character, and pulse rate provide late information about the severity of blood loss. Subsequently, the appearance of hypotension and other signs and symptoms of shock does not mark the beginning of circulatory compromise but rather represents the beginning of decompensation when it may be too late to introduce effective life-saving interventions.

Study objective

The objective of this study is the investigate whether near-infrared spectroscopy in combination with a vascular occlusion test is able to detect the early changes in muscular oxygenation in a model of controlled hypovolemia

induced by lower body negative pressure.

Study design

With the use of a neoprene skirt, designed to form an airtight seal between the subject and the chamber, the application of negative pressure to the lower body (below the iliac crest) results in a redistribution of blood away from the upper body (head and heart) to the lower extremities and abdomen. This model, therefore, provides conditions of controlled, experimentally induced hypovolemic hypotension, offering a unique method for investigating new monitoring devices, such as the multi-depth InSpectra (see below for description). Although absolute equivalence between the magnitudes of negative pressure applied and actual blood loss cannot be determined at this time, review of available human and animal data has revealed ranges of effective blood loss (or fluid displacement) caused by LBNP. Considering the magnitude of induced central hypovolemia, Soller et al. have previously proposed that 10*20 mm Hg negative pressure produces hemodynamic responses equivalent to those resulting from blood loss of 400*550 mL, 20*40 mm Hg LBNP induces hemodynamic responses equivalent to blood loss of 550*1000 mL, and >40 mm Hg LBNP induces responses equivalent to blood loss of >1000 mL.
Each subject will be reported to the laboratory for a progressive LBNP protocol that is designed to test his or her tolerance to experimentally induced hypotensive hypovolemia. The subject will first be instrumented with noninvasive devices for hemodynamic and tissue oxygenation measurements (described below).
The LBNP protocol consists of a 5-min baseline period followed by 5 min of chamber decompression to -20 (5 min), -40 (15 min, including a 3-min vascular occlusion test), and -60 mm Hg (5 min) until either the onset of cardiovascular collapse or the completion of 5 min at -60 mm Hg. Cardiovascular collapse is defined by one or a combination of the following criteria: a) a precipitous fall in systolic blood pressure (SBP) >15 mm Hg and/or a sudden bradycardia; b) progressive diminution of SBP <70 mm Hg; or c) voluntary subject termination due to discomfort from presyncopal symptoms, such as sweating, nausea, dizziness, or gray-out. At the onset of cardiovascular collapse, the chamber vacuum will be released to ambient pressure to rapidly restore blood flow and blood pressure. To ensure subject safety, an Advanced Cardiac Life Support provider or physician will be present in the laboratory during all LBNP tests.

Study burden and risks

During the gradual application of lower body negative pressure lightheadedness could ensue. The volunteer participants will have direct access to a push button system that can terminate the lower body negative pressure and thus stop the experiment immediately. NIRS and the VOT are both noninvasive, painless and entirely safe techniques. During the experiments a trained physician will be present at all times to ensure the safety of each participant.

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

Healthy
Normotensive
Non-smoking
> 18 years

Exclusion criteria

Smoking
Diabetes
Hypertension

Cardiovascular disease

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL26723.018.09