Organ protection by noble gases * Helium induced Early and Late Preconditioning (HELP) in human endothelium

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The aim of this clinical study is to investigate whether the non-anaesthetic noble gas helium induces EPC and LPC of human endothelium in vivo.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON32361

Source
ToetsingOnline

Brief title
Helium induced preconditioning

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
perfusion dysregulation, vascular ischemia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,International Anesthesia Research Society

Intervention

Keyword: endothelium, Helium, preconditioning

Outcome measures

Primary outcome

Main study parameters/endpoints: Endothelial preconditioning with helium will be investi¬gated by measurement of forearm blood flow using the venous occlusion plethysmography model. Primary end-point is blood flow and reactive hyperemia before and after I/R with or without helium inhalation after stimulation with either serotonin (5HT) as an endothelium-dependent or sodium nitroprusside (SNP) as an endothelium-independent vasodilator.

Secondary outcome

Secondary parameters will be measurement as endothelial adhesion molecules on leukocytes. Therefore, blood samples will be collected at different time points.

Study description

Background summary

Supported by experimental and clinical data showing reduction of endothelial cell damage by noble gases in human umbilical vein endothelial cells as well as by subanesthetic concentrations of sevoflurane in humans subjected to ischemia-reperfusion, we hypothesize that the noble gas helium induces early (EPC) and late (LPC) preconditioning in human endothelium in vivo.

Study objective

The aim of this clinical study is to investigate whether the non-anaesthetic

noble gas helium induces EPC and LPC of human endothelium in vivo.

Study design

single center, randomized, open label, observational study. In this combined clinical-laboratory investigation, investigators of laboratory parameters will be blinded. Blinding of the patient is not possible as the patient will recognize changes in voice (shortly higher voice during helium inhalation) and therefore will know that she/he inhales helium.
Study population: healthy human volunteers, 18 - 65 yr old

Intervention

We will compare a control group (group 1, CON) to volunteers who will undergo ischemia and reperfusion of the forearm in the absence (group 2, I/R) or presence of helium inhalation (3*5 min, 79%) 15 min (group 3, EPC) or 24 hours (group 4, LPC) before forearm ischemia. Another group will undergo ischemic preconditioning and will serve as positive control (group 5, IPC).

Study burden and risks

Volunteers will undergo helium inhalation (79% helium, 21% oxygen), which has until now not reported to have no relevant cardiovascular, pulmonary, allergic or other side effects. A gas-mixture of helium with oxygen (heliox) is already in clinical use for patients with severe asthma or for children undergoing mechanical ventilation. Volunteers will experience a transiently higher voice after helium inhalation. Cannulation of an artery as well as venous access lines will be placed under local anesthesia and aseptic conditions (best clinical practice procedures). Four to five blood samples (10 ml each) will be drawn from inserted cannulas. Participation will include a whole day and a telephone interview the following day. Patients undergoing LPC have to come to the AMC one day before the measurements will take place to inhale 3*5 min helium 79% / oxygen 21%. On the day of participation, a physical examination (cardiopulmonary system) will be performed by a physician.

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 volunteers aged 18-65 years, informed consent

Exclusion criteria

untreated arterial hypertension, known renal impairment, liver disease, cardiovascular disease (arterial hypertension, angina, previous myocardial infarction, history of stroke), history of diabetes mellitus, coagulatopathy (PTT > 1.5 times control), anti coagulation drugs, antihypertensive drugs, contra indication or intolerance to any used substance

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2008
Enrollment:	55
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Heliox 21
Generic name:	Heliox 21
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-11-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-04-2009
Application type:	Amendment
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
EudraCT	EUCTR2007-006233-14-NL
CCMO	NL20607.018.07

Study results

Date completed: 16-08-2012

Actual enrolment: 50

Summary results
Trial is onging in other countries