Organ protection by helium gas inhalation: protective factors in the blood

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26549

Source
NTR

Brief title
HeCAV

Health condition

Ischemia/reperfusion injury
ischemie/reperfusie schade

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam, Department of Anesthesiology
Source(s) of monetary or material Support: Society of Cardiovascular Anesthesiologists, Department of Anesthesiology, Academic Medical Center Amsterdam

Intervention

Outcome measures

Primary outcome

- Cell damage such as LDH, apoptosis markers

- Expression of Cav-1 and Cav-3 in blood

Secondary outcome

- If Cav-levels are significantly different after helium inhalation, cells will be incubated with cav-antibodies

Study description

Background summary

Helium induces organ protection, but currently its mechanisms of action are unclear. This trial investigates the underlying mechanisms of helium-induced protection. We hypothesize that helium inhalation results in the release of "protective" mediators in the blood, which are transported to tissue at risk for ischemia/reperfusion damage. This is investigated in the current study in which healthy volunteers will breathe helium, after which blood will sampled. Different cells exposed to hypoxia/reoxygenation in vitro, will be incubated with this blood, and we will investigate whether a reduction in cell damage can be found.

Study objective

We hypothesize that inhalation of helium gas induces release of protective factors in the blood, which can be used to protect different cell types against ischemia/reperfusion injury.

Study design

timepoints blood sampling: T0 (baseline), T1 (directly after inhalation), T2 (6 h after inhalation), T3 (24 h after inhalation)

Intervention

- Inhalation of helium or air

- Blood sampling by venous puncture

Contacts

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Eligibility criteria

Inclusion criteria

non-smoking, healthy male volunteers, aged 20-55 years

Exclusion criteria

-Active smoking or smoking in the previous six months

-Alcohol abuse or use of recreational drugs

-Any allergic reaction on medication in the past

-Presence of a chronic disease that is under current medical observation and needs pharmacological treatment, e.g. asthma, high blood pressure or diabetes

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-04-2014
Application type:	First submission

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
NTR-new	NL4367
NTR-old	NTR4507
Other	METC nummer : 2014_045

Study results

Summary results

Smit KF, Oei GTML, Stroes ES, Nieuwland R, Schlack W, Hollmann MW, Weber NC, Preckel B:

Helium induces
preconditioning in the human endothelium in vivo. Anesthesiology 2013 Jan;118(1):95-104

Oei GTML, Smit KF, van de Vondenvoort D, Wieland CW, Hollmann MW, Preckel B, Weber NC; The effect of helium inhalation on the innate and early adaptive immune system ex vivo. J Transl Med 2012;10:201

Oei GTML, Huhn R, Heinen A, Hollmann MW, Schlack WS, Preckel B, Weber NC: Helium-induced cardioprotection of healthy and hypertensive rat myocardium in vivo. Eur J Pharmacol 2012; 684:125-131

Berger MM, Huhn R, Oei GTML, Heinen A, Winzer A, Preckel B, Weber NC, Schlack W, Hollmann MW: Hypoxia induces late preconditioning in the rat heart in vivo. Anesthesiology 2010; 113:1351-60

Oei GTML, Weber NC, Hollmann MW, Preckel B: Cellular effects of helium in different organs. Anesthesiology 2010; 112:1503-10.

Huhn R HA, Weber NC, Kerindongo R, Oei GTML, Hollmann MW, Schlack W, Preckel B: Helium-induced early preconditioning and postconditioning is abolished in obese Zucker rats in vivo. J Pharmacol Exp Ther 2009; 329:600-7