The effect of helium on the immune system ex vivo

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The aim of this study is to evaluate whether a 30-minute episode of helium breathing in humans affects the ability of the immune system to respond to ex vivo stimulation in whole blood taken from healthy volunteers.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33293

Source
ToetsingOnline

Brief title
HeLIX

Condition

- Other condition

Synonym
Immunomodulating effects

Health condition

Immuun modulerend effect

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Helium, Immuneresponse

Outcome measures

Primary outcome

The main parameters of this study will be proinflammatory cytokines determined

after ex vivo stimulation of whole blood. The cytokines are: IL-1beta, IL-6,

TNF-alfa, the chemokine IL-8, T-cell products IL-2 and INF-gamma and a

neutrophil degranulation product: elastase.

Secondary outcome

not applicable

Study description

Background summary

Various experimental studies have shown protective effects of helium inhalation on ischemia/reperfusion damage in myocardial and cerebral tissue. Based on these findings, we want to investigate whether an extended episode of helium inhalation has any effects on the immune response.

Study objective

The aim of this study is to evaluate whether a 30-minute episode of helium breathing in humans affects the ability of the immune system to respond to ex vivo stimulation in whole blood taken from healthy volunteers.

Study design

Explorative study with a cross-over design, using the principle of balanced assignment. In this combined clinical and laboratory study, researchers

investigating immuneparameters in the laboratory will be blinded. Blinding of patients is not possible, due to changes in voice after inhalation of heliumgas.

Intervention

Volunteers will be studied during two separate days, in which they will breath heliox or room air for 30 min using a special, sealed mask.

Study burden and risks

All volunteers have to undergo two experimental *cycles*: one with heliox inhalation and one with inhalation of normal room air. Between the experimental cycles there will be an episode of at least two weeks. Each cycle includes one whole day in the AMC (± 8 hours) and blood donation the next day in the morning. On the day of participation, a physical examination (cardiopulmonary system) will be performed by a physician. Twelve hours before the start of the experimental cycle, the volunteer is not allowed to drink coffee or other caffeine containing drinks, or to smoke. Doing any kind of sports on the night before the experimental day in the AMC, or the night before the second day is also prohibited.
On experimental day, the volunteers have to stay in the research room in which circumstances will be as standardized as possible. Until after the third time point of blood sampling, the volunteers have to stay seated in a chair and they will be offered time to read. After that, they will receive a lunch that will be the same for every volunteer. After time point 3, the volunteers are allowed to walk around but they have to stay within the AMC.
Volunteers will undergo helium inhalation, with concentration 79% helium and 21% oxygen. Until now, no relevant cardiovascular, pulmonary, allergic or other side effects of helium inhalation have been reported. A gas mixture of helium and oxygen (heliox) is already used for clinical purposes, such as patients with severe asthma or for children undergoing mechanical ventilation. Volunteers will experience a transiently higher voice after helium inhalation. Each blood withdrawal will be taken from a separate puncture site performed by a physician with extensive experience in this field, such as an anesthesiologist. For this study, the blood sampling cannot take place through a venous access line. In total, the volunteer gives 126 ml for one experimental cycle (2 days) and a total of 252 ml for the whole experiment (4 days).

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

Non-smoking, healthy, male volunteers, aged 18-45 years, informed consent

Exclusion criteria

Smoking, current or in the past six months
Alcohol or drug abuse
Allergic reaction to medication in past medical history
Chronic medication use that could influence the immune system
Presence of any condition that could influence the immune system

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Heliox 21
Generic name:	Heliox 21

Ethics review

Approved WMO Date:	05-02-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-08-2011
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

ID: 21602
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2009-010078-39-NL
CCMO	NL26824.018.09
OMON	NL-OMON21602