The effect of helium on the immune system.

Gepubliceerd: 04-01-2010 Laatst bijgewerkt: 19-03-2025

Primary objective: Does a 30-minute episode of helium breathing in humans decrease the amount of pro-inflammatory cytokines and chemokines produced in whole blood after immunostimulation ex vivo?

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21602

Bron
NTR

Verkorte titel
HeLIX

Aandoening

immune response, helium

Ondersteuning

Primaire sponsor: Academic Medical Centre, Amsterdam
Overige ondersteuning: Academic Medical Centre, Amsterdam, Department of Experimental and Clinical Anesthesiology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Proinflammatory cytokines in whole blood: Il-1beta, Il-6, TNF-alpha;

2. Chemokine: Il-8, T-cell products Il-2, INF-gamma;
3. Neutrophil degranulation product: elastase.

Toelichting onderzoek

Achtergrond van het onderzoek

Various studies have shown protective effects of helium inhalation on ischemia/reperfusion damage in mycoardial and cerebral tissue. Based on these findings we want to investigate whether an extended episode of helium inhalation has any effect on the immune response. This is an explorative study with a cross-over design, using the principle of balanced assignment in a group of 12 healthy, male volunteers. The main endpoints are proinflammatory cytokines, chemokines, T-cell products and the neutrophil product elastase.

Doel van het onderzoek

Primary objective: Does a 30-minute episode of helium breathing in humans decrease the amount of pro-inflammatory cytokines and chemokines produced in whole blood after immunostimulation ex vivo?

Onderzoeksopzet

T0 = 15 mins before start of helium or room air breathing;

T1 = After 25 mins of helium/room air breathing;

T2 = 60 mins after helium/room air breathing;

T3 = Two hours after helium/room air breathing;

T4 = Six hours after helium/room air breathing;

T5 = 24 hours after helium/room air breathing.

Onderzoeksproduct en/of interventie

1. Helium or normal air breathing through a mask for 30 minutes;

2. Blood sampling through seperate puncturing sites.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Non-smoking, healthy, male volunteers, aged 18-45 years old.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Smoking; current or in past six months;

2. Alcohol or drug abuse;

3. Allergic reaction to medication in past medical history;

4. Chronic medication or presence of any condition that could influence the immune system.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2009
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-01-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33293
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2034
NTR-old	NTR2152
CCMO	NL26824.018.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33293

Resultaten

Samenvatting resultaten
N/A