Tolerability and physiological effects of elevated inspired carbon dioxide (CO2) concentrations in human volunteers

Gepubliceerd: 08-01-2015 Laatst bijgewerkt: 19-03-2025

An observational study looking into the effect of elevated levels of inspired carbon dioxide on physiological, behavioral and cognitive functioning.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22471

Bron
Nationaal Trial Register

Verkorte titel
TOPofCO2

Aandoening

Safety and Tolerability of CO2

Ondersteuning

Primaire sponsor: Leiden University Medical Centre
Overige ondersteuning: CATO-2: financial support

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Safety: reaching pre-defined stopping rules pertaining to: significant bloodgas changes (pH,

pCO2, pO2), excessive changes in heartrate or bloodpressure, severe side-effects (i.e. headache, nausea, sedation)

Tolerability: time to either subject indicating he wants to discontinue the experiment, or deemed necessary to discontinue the experiment by the investigator/attending physician

Toelichting onderzoek

Achtergrond van het onderzoek

An observational study looking into the effects of elevated levels of inspired Carbon dioxide in healthy volunteers. With special focus on physiological, behavioral and cognitive paramaters.

Doel van het onderzoek

An observational study looking into the effect of elevated levels of inspired carbon dioxide on physiological, behavioral and cognitive functioning.

Onderzoeksopzet

Measurements will take place at 5 or 10 minute interval for: Bloodgas, evaluation of side effects, cognitive tests.

Continuous measurements are collected for:
Cardiac output; Invoss; BIS; levels of inspired gas

Onderzoeksproduct en/of interventie

Escalating exposure duration 10,30 and 60 minutes for the first three concentrations 6%, 7.5% and 9% inspired CO2. Followed by 5 minutes 100% oxygen. For each combination of duration and concentration 6 subjects were included. Escalation af concentration only took place after all durations for this concentration were completed without the occurence of SAE's.

For the concentrations 10% and 12% the maximum duration of exposure was 10 minutes. Followed by 5 minutes 100% oxygen. 10 subjects for the 10% and 10 subjects for the 12% CO2 exposure were included

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age of 18 to 35 years (inclusive);

2. Body Mass Index (BMI) between 18 and 25 kg/m2 (inclusive) and body weight between 50 kg and 100 kg (inclusive);

3. Subject is able to read and understand the written consent form, complete study-related procedures, and communicate with the study staff;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Clinically relevant abnormal history of physical and mental health, as determined by

medical history taking and physical examinations obtained during the screening visit and/or prior to the administration of the initial dose of the study drug (as judged by the investigator);

2. A semi recumbent systolic blood pressure of >150 mmHg and/or diastolic blood pressure of > 90 mmHg at screening;

3. History of alcoholism or substance abuse within three years prior to screening;

4. Use of medication during the study period;

5. Subjects smoking > 10 cigarettes/day or equivalents

6. Participation in an investigational drug trial in the 3 months prior to administration of the initial dose of study drug or more than 4 times per year;

7. Any other condition that in the opinion of the investigator would complicate or compromise the study, or the wellbeing of the subject, including pulmonary disease such as a history of asthma.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-06-2013
Aantal proefpersonen:	74
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-01-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40519
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4955
NTR-old	NTR5077
CCMO	NL42820.058.12
OMON	NL-OMON40519

Resultaten

Samenvatting resultaten
NA