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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22471

Source
Nationaal Trial Register

Brief title
TOPofCO2

Health condition

Safety and Tolerability of CO2

Sponsors and support

Primary sponsor: Leiden University Medical Centre
Source(s) of monetary or material Support: CATO-2: financial support

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Cognitive functioning: p-deletion test

Cerebral oxygenation: Invos

Bispectral imaging changes: BIS

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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;

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-06-2013
Enrollment:	74
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-01-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40519
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
NA