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

Published: 07-03-2013
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Measuring the effects of CO2 inhalation (6, 8 and 10%) on the body: EEG, heart rate, blood pressure, cardiac output, ECG, oxygen content in the brain, sedation, cognition, nausea.Amendment:Measuring the effects of CO2 inhalation (10% and 12%) on the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON40519

Source
ToetsingOnline

Brief title
TOPofCO2

Condition

- Other condition

Synonym
Physiological effect of carbon dioxide

Health condition

testen van de tolerantie van CO2 inhalatie

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Koninklijke Shell BV

Intervention

Keyword: Carbon dioxide, inhalatie, toxicity

Outcome measures

Primary outcome

Changes in EEG, heart rate, blood pressure, cardiac output, ECG, oxygen

content in the brain, sedation, cognition, nausea.

Secondary outcome

-

Study description

Background summary

CO2 is a greenhouse gas. To prevent further global warming liquid CO2 is pumped into the ground. Problems/disasters around these injections can lead to the release of large amounts of CO2 into the atmosphere. This can lead to suffocation (due to lack of oxygen) but there are also direct effects of CO2 on the body. These direct effects are investigated in this study during inhalation of 6, 8 and 10% CO2 in healthy volunteers.

Amendment:
additonal cohort in which the effects of 10% and 12% CO2 will be investigated

Study objective

Measuring the effects of CO2 inhalation (6, 8 and 10%) on the body: EEG, heart rate, blood pressure, cardiac output, ECG, oxygen content in the brain, sedation, cognition, nausea.

Amendment:
Measuring the effects of CO2 inhalation (10% and 12%) on the body: EEG, heart rate, blood pressure, cardiac output, ECG, oxygen content in the brain,

sedation, cognition, nausea.

Study design

Open and descriptive

Study burden and risks

The burden covers the possible occurrence an nausea / vomiting, headache, sedation and possibly epileptiform activity. This is a certain amount of load.

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

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 well being of the subject, including pulmonary disease such as a history of asthma.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-06-2013

Enrollment:	74
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-06-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-02-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-07-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 22471
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL42820.058.12
OMON	NL-OMON22471