An observational study into the occurrence of panic attacks after inhalation of 65% oxygen and 35% carbon dioxide.

No registrations found.

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

Summary

ID

NL-OMON26851

Source
NTR

Brief title
35% CO2 single versus double inhalation study

Health condition

Panic disorders

Sponsors and support

Primary sponsor: CHDR
Source(s) of monetary or material Support: CHDR

Intervention

Outcome measures

Primary outcome

To investigate the difference in response between single and double vital capacity 35%

CO2/65% O2 in terms of the occurrence of PA’s in healthy subjects as measured with the Panic Symptoms List-IV (PSL-IV) and VAS subjective anxiety and fear.

Secondary outcome

• explore whether the occurrence of PA’s on a single vital capacity inhalation 35% CO2/65% O2 predicts the occurrence of PA’s on a double vital capacity inhalation 35% CO2/65% O2.

• explore the temporal stability of the occurrence of 35% CO2/65% O2-induced PA’s in subjects who develop PA’s on a single vital capacity inhalation and subsequently receive a double vital capacity inhalation.

• explore the effects of single and double breath 35% CO2/65% O2 on heart rate, blood pressure, respiratory rate.

• explore differences in sensitivity to 35% CO2/65% O2 between male and female subjects

Study description

Background summary

Maastricht Instruments in collaboration with Maastricht University has recently developed the CO2 tolerance tester (CTT). The CTT
is a research instrument that safely and reliably induces PA’s by the protocolized administration of inhaled 35% CO2. In addition, the CTT simultaneously measures physiological changes associated with CO2-induced ANS activation such has heart rate and blood
pressure. In contrast to previous experimental CO2 set ups, the CTT yields integrated real time information on ANS panic-related
parameters following acute CO2 inhalation which can be readily combined with subjective assessments such as fear intensity. The CTT is particularly relevant to research in the field fear-related psychiatric disorders and is a potentially useful tool in CNS drug development with novel anxiolytic compounds.To the best of our knowledge no study has been previously published that compares single and double vital capacity 35% CO2
inhalation in a single study. Therefore, we aim to investigate the panicogenic effects of a single vs. a double vital capacity method 35% CO2 in healthy volunteers. We hypothesize that 35% CO2 double vital capacity inhalation is associated with a higher percentage of subjects experiencing a panic attack compared to single vital capacity inhalation. Subjects will be recruited in the Netherlands.

Study objective

To investigate the difference in response between single and double vital capacity 35% CO2/65% O2 in terms of the occurrence of PA’s in healthy subjects as measured with the

Panic Symptoms List-IV (PSL-IV) and VAS subjective anxiety and fear.

Study design

Screening (physical examination medical history, urine analysis, vital signs)

Intervention

NA

Contacts

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Eligibility criteria

Inclusion criteria

• Informed consent in writing.

• Healthy male or female aged between 18 and 55 years (inclusive) at screening.

• BMI of 18-32 kg/m2 (inclusive).

• Non-smoker for at least 3 months.

• Ability to communicate adequately with the Investigator in the Dutch language and is willing to comply with the study restrictions.

Exclusion criteria

• Current or past history of any psychiatric disorder as classified according to DSM-IV or DSM 5.

• Current or past history of alcohol or any substance abuse or dependence disorder within the past 12 months.

• Presence of panic disorder as classified by DSM-IV and diagnosed by a psychiatrist or classified by the module Panic Disorder (E) of the MINI International Neuropsychiatric Interview during screening.

• Subject drinks, on average, more than 8 cups of tea/coffee/cocoa/cola/caffeinated beverages (e.g., energy drink) per day.

• Subject has a clinically significant acute illness within 7 days prior to the CO2 challenge.

• Systolic blood pressure (SBP) greater than 140 or less than 90 mm Hg, and diastolic blood pressure (DBP) greater than 90 or less than 50 mm Hg

• Clinically significant ECG abnormalities.

• Clinically significant abnormality of the lungs (e.g. COPD, asthma, lung fibrosis) and hematologic diseases concerning hemoglobin (e.g. thalassemia and sickle cell disease).

• Important cardiovascular history, or suspicion of infarct, cardiomyopathy, cardiac failure, TIA, angina pectoris, cardiac arrhythmias, CVA.

• Personal or familial history of cerebral aneurysm.

• Pregnancy as demonstrated by urine pregnancy test during screening or at each study day.

• Use of any psychotropic drugs.

• Have a urine drug screen detecting illicit drug of abuse (morphine, benzodiazepines, cocaine, amphetamine, THC) or a positive alcohol breath test at screening or each study day.

Study design

Design

Study type:	Observational non invasive

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45528
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6244
NTR-old	NTR6424
CCMO	NL61306.056.17
OMON	NL-OMON45528

Study results