

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON26851

### Source

Nationaal Trial Register

### Brief title

35% CO<sub>2</sub> 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%

CO<sub>2</sub>/65% O<sub>2</sub> 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% CO<sub>2</sub>/65% O<sub>2</sub> predicts the occurrence of PA's on a double vital capacity inhalation 35% CO<sub>2</sub>/65% O<sub>2</sub>.
- explore the temporal stability of the occurrence of 35% CO<sub>2</sub>/65% O<sub>2</sub>-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% CO<sub>2</sub>/65% O<sub>2</sub> on heart rate, blood pressure, respiratory rate.
- explore differences in sensitivity to 35% CO<sub>2</sub>/65% O<sub>2</sub> between male and female subjects

## Study description

### Background summary

Maastricht Instruments in collaboration with Maastricht University has recently developed the CO<sub>2</sub> tolerance tester (CTT). The CTT is a research instrument that safely and reliably induces PA's by the protocolized administration of inhaled 35% CO<sub>2</sub>. In addition, the CTT simultaneously measures physiological changes associated with CO<sub>2</sub>-induced ANS activation such as heart rate and blood pressure. In contrast to previous experimental CO<sub>2</sub> set ups, the CTT yields integrated real time information on ANS panic-related parameters following acute CO<sub>2</sub> inhalation which can be readily combined with subjective assessments such as fear intensity. The CTT is particularly relevant to research in the field of 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% CO<sub>2</sub> inhalation in a single study. Therefore, we aim to investigate the panicogenic effects of a single vs. a double vital capacity method 35% CO<sub>2</sub> in healthy volunteers. We hypothesize that 35% CO<sub>2</sub> 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% CO<sub>2</sub>/65% O<sub>2</sub> 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/m<sup>2</sup> (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/cafeinated beverages (e.g., energy drink) per day.
- Subject has a clinically significant acute illness within 7 days prior to the CO<sub>2</sub> 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