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

Gepubliceerd: 02-05-2017 Laatst bijgewerkt: 15-05-2024

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.

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

## Samenvatting

### ID

NL-OMON26851

**Bron**
Nationaal Trial Register

**Verkorte titel**
35% CO2 single versus double inhalation study

**Aandoening**

Panic disorders

### Ondersteuning

**Primaire sponsor:** CHDR
**Overige ondersteuning:** CHDR

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

NA

# Contactpersonen

## Publiek

Gabriel Jacobs
Zernikedreef 08

Leiden 2333 CL
The Netherlands
+31 71 5246 400

## Wetenschappelijk

Gabriel Jacobs
Zernikedreef 08

Leiden 2333 CL
The Netherlands
+31 71 5246 400

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-05-2017 |
| Aantal proefpersonen: | 20 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 02-05-2017 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45528
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL6244 |

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

# Resultaten