

Diagnosing Panic Disorder in the respiratory setting: Validation of the 35% CO2 challenge as a diagnostic tool

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Validation of the 35% CO2 challenge as a diagnostic instrument within the respiratory setting and the assessment of the percentage of cases in which no or only a partial explanation can be given for the complaints within the pulmonological setting,...

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|------------------------------|--------------------------------|
| Ethical review | Approved WMO |
| Status | Recruiting |
| Health condition type | Anxiety disorders and symptoms |
| Study type | Observational invasive |

Summary

ID

NL-OMON31832

Source

ToetsingOnline

Brief title

Further validation of the 35% CO2 challenge

Condition

- Anxiety disorders and symptoms

Synonym

anxiety attacks, Panic Anxiety

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 35% CO₂ challenge, diagnose, Panic Disorder, validation

Outcome measures

Primary outcome

The occurrence or non-occurrence of a panic attack induced by the 35% CO₂ challenge as measured on the Visual Analogue Scale of Anxiety and the Panic Symptom List

Secondary outcome

HADS score, respiratory measures

Study description

Background summary

Respiratory symptoms frequently occur during panic attacks. As a result, undiagnosed Panic Disorder patients regularly unjustly end up in the respiratory setting. Due to a lack of specific psychiatric knowledge by the medical specialist, the possibility of an anxiety disorder (i.e. Panic Disorder) is often overlooked. The 35% CO₂ challenge could make it possible to easily diagnose Panic Disorder within the somatic setting. The current study aims at validating the 35% CO₂ challenge within the respiratory setting and at assessment of the percentage of cases in which no or only a partial explanation can be given for the complaints within the pulmonological setting, and a Panic Disorder is responsible.

Study objective

Validation of the 35% CO₂ challenge as a diagnostic instrument within the respiratory setting and the assessment of the percentage of cases in which no or only a partial explanation can be given for the complaints within the pulmonological setting, and a Panic Disorder is responsible.

Study design

Fixed design with the interview always first. Both parts will be performed by

two different researchers, blinded for the diagnosis as are the subjects.

Study burden and risks

The burden of the study is low as the research takes effectively maximally 1 hr in time. There is a small chance of headache. It is expected that in a number of subjects Panic Disorder will be diagnosed. In this case, or in case of another psychiatric disorder, the subject will be informed about this and options for treatment will be discussed.

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

Admission at the azM outpatient clinic of Respiratory Medicine
No or limited pulmonary explanation for the reported symptoms
Good general health

Exclusion criteria

Presence of respiratory disease*
History or presence of cardiovascular disease
Personal or familial history of cerebral aneurysm
Hypertension (syst: > 180; diast. > 100)
Pregnancy
Epilepsy
Use of psychopharmaca;*Respiratory disease objectified as: FEV1 < 60% pred, RV >150% pred or DLCO < 60% pred.

Study design

Design

| | |
|---------------------|---------------------------------|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

Recruitment

| | |
|---------------------------|------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 14-01-2009 |
| Enrollment: | 60 |
| Type: | Actual |

Ethics review

Approved WMO

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|--------------------|---|
| Date: | 26-05-2008 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO | |
| Date: | 10-11-2008 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL22124.068.08 |