# Validity of the metronome-paced hyperventilation test to detect dynamic hyperinflation

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The primary objective of this current proposal is to test validity of the MPH test to detect DH. Validity is analyzed by comparing MPH-induced DH with DH induced by a symptom-limited incremental cycle exercise test.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Respiratory disorders NEC |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON34449

**Source**
ToetsingOnline

**Brief title**
MPH to detect DH

### Condition

- Respiratory disorders NEC

**Synonym**
dynamic air trapping, dynamic hyperinflation

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** Nederlands Astmafonds

## Intervention

**Keyword:** dynamic hyperinflation, metronome-paced hyperventilation

## Outcome measures

### Primary outcome

The change in IC after MPH and exercise: MPH- and exercise- induced DH.

### Secondary outcome

not applicable

# Study description

### Background summary

During exercise in COPD patients, air trapping causes an increase in end expiratory lung volume (EELV) and a decrease in inspiratory capacity (IC). This is called dynamic hyperinflation (DH) and is determined by measuring the IC before and during exercise. Various studies have used symptom-limited incremental cycle ergometry to detect DH. Because this method to determine DH is relative expensive, time consuming and uncomfortable for patients, new methods have been sought. DH induced by metronome-paced hyperventilation (MPH) for 20 seconds at twice the resting respiratory rate was compared to DH induced by cycle ergometry in patients with COPD and a similar significant decrease in IC was found. However, this has never been confirmed by other investigators. Currently, the repeatability and validity of the MPH test is studied in COPD patients by our research group (CMO dossier nr: 2008/322, ABR nr: NL25920.091.08). However, it is unknown whether the MPH test can discriminate between hyperinflators and non-hyperinflators. Therefore, also age-matched healthy volunteers are needed. The hypothesis is that these healthy subjects are not susceptible to DH, and therefore do not show a decrease in IC during the exercise test, nor after MPH.

### Study objective

The primary objective of this current proposal is to test validity of the MPH test to detect DH. Validity is analyzed by comparing MPH-induced DH with DH induced by a symptom-limited incremental cycle exercise test.

### Study design

This study is an instrumental study, because it evaluates the MPH test. The healthy subjects perform lung function testing, the MPH test and a symptom-limited incremental cycle exercise test.

**Study burden and risks**

In case of participation, all tests for one subject are planned on one day with a maximal span of two hours. The healthy subjects themselves do not benefit from the study. However, by including healthy subjects, the MPH-test can be validated providing a new, more easy tool to detect DH. Because subjects are asked to cycle with increasing load until their maximal exercise capacity is reached, there is a risk of unknown underlying cardiac problems becoming overt. Therefore, this test is always supervised by qualified, experienced personnel.

# 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

Non-smoking capable subjects, aged 50-75 years, with a FEV1/VC ratio (forced expiratory volume in one second divided by the vital capacity) > 0.7 and FEV1 >= 80% of predicted

### Exclusion criteria

Subjects with asthma history or with lung problems of any kind, or with severe exercise limiting cardiac or neuromuscular disorders

## Study design

### Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 10-09-2010 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 03-08-2010 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL32779.091.10 |