

# Effect of Dynamic Hyperinflation on Pulmonary Hemodynamics and Right Ventricular function in Chronic Obstructive Pulmonary Disease

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Questions/aims To study the effects of dynamic hyperinflation on pulmonary hemodynamics and right and left ventricular function we formulated the following questions. Do COPD patients with dynamic hyperinflation have a more impaired response of stroke...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Respiratory disorders NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON34856

### Source

ToetsingOnline

### Brief title

Effect of Dynamic Hyperinflation on Pulmonary Hemodynamics

### Condition

- Respiratory disorders NEC

### Synonym

COPD, emphysema

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

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

## Intervention

**Keyword:** COPD, Dynamic Hyperinflation, Pulmonary hemodynamics, Right Ventricular Function

## Outcome measures

### Primary outcome

Do COPD patients with dynamic hyperinflation have a more impaired response of stroke volume and cardiac output at exercise than COPD patients with a similar GOLD classification without dynamic hyperinflation?

- SV using direct Fick method at every level of exercise
- Inspiratory capacity (IC)

What is the effect of dynamic hyperinflation on right and left ventricular function in COPD?

- RV pressure/volume curves derived from RHC (pressure) and cMRI (volumes)

What is the effect of dynamic hyperinflation on systemic oxygen delivery and extraction?

- Arterial and venous blood samples

### Secondary outcome

Does the reduction of dynamic hyperinflation in COPD by Heliox (Helium-Oxygen) inhalation lead to afterload reduction of the right ventricle and by that to improvement of the cardiac output augmentation during exercise?

- SV, IC and blood samples during Heliox test
- Pressure measurements of RHC

What is the influence of dynamic hyperinflation and stroke volume impairment on the outcomes of the rehabilitation program.

- Lung function, exercise capacity, quality of life scores during and after rehabilitation program.

## Study description

### Background summary

Lung hyperinflation is defined as increased air volume at the end of a normal, spontaneous expiration, called the End-Expiratory Lung Volume (EELV), and develops in COPD because of a decrease in lung compliance due to irreversible destructive changes of emphysema.

During exercise the rate and depth of inspiration normally increase. In COPD, airflow limitation due to the airway obstruction together with lowered expiration time during exercise will lead to an insufficient emptying of the lung at expiration, resulting in a progressive increase of EELV. This \*dynamic\* hyperinflation (DH), which is dependent of expiratory airflow and expiratory time [1] leads to a disproportional increase in the work of breathing and dyspnoea sensation. [2] Recently it was found that dynamic hyperinflation is present even during daily activities in COPD patients.[3] A direct consequence of dynamic hyperinflation is increased intrathoracic pressure at end of expiration. Although the effects of increased intrathoracic pressure on pulmonary hemodynamics are well studied in healthy subjects in the so called Valsalva manoeuvre, where they lead to an increase in pulmonary artery pressure and a drop in cardiac output. However, the effects on right ventricular function are unknown and in addition to that, the situation in dynamic hyperinflation is different from the Valsalva manoeuvre since increased expiratory pressures are followed within seconds by a decreased pressure at inspiration. The effects of these pressure swings between in- and expiration on the hemodynamics and right ventricular function are unknown. Our central

hypothesis is that dynamic hyperinflation induces an afterload increase for the right ventricle and impairs stroke volume augmentation in exercise.

## **Study objective**

Questions/aims

To study the effects of dynamic hyperinflation on pulmonary hemodynamics and right and left ventricular function we formulated the following questions.

Do COPD patients with dynamic hyperinflation have a more impaired response of stroke volume and cardiac output at exercise than COPD patients with a similar GOLD classification without dynamic hyperinflation?

What is the effect of dynamic hyperinflation on right and left ventricular function in COPD?

What is the effect of dynamic hyperinflation on systemic oxygen delivery and extraction?

Does the reduction of dynamic hyperinflation in COPD by Heliox (Helium-Oxygen) inhalation lead to afterload reduction of the right ventricle and by that to improvement of the cardiac output augmentation during exercise?

What is the influence of dynamic hyperinflation and stroke volume impairment on the outcomes of the rehabilitation program.

## **Study design**

Observational study.

RHC at rest, maximal exercise test and a submaximal exercise while breathing Heliox  
cardiac MRI at rest and during submaximal exercise.

## **Study burden and risks**

Patients will be hospitalized for 2 days. The main burden for the patients will be the RHC together with an esophageal balloon and arterial canula. Apart from that, there is one moment of blood sampling. During the 2 days, patients have to perform 1 maximal exercise test and 2 submaximal exercise test.  
The risks are the same as the known risks for RHC and arterial cannulation.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

COPD GOLD 2-4

Suspected pulmonary hypertension.

Patients with progressive complains and/or unexplained complains with stable lungfunction or cardiovascular limitations during exercise test in who an RHC is clinical indicated

### Exclusion criteria

History of systemic hypertension

History of left sided cardiac failure

Signs of left ventricular dysfunction and/or valvular disease on Doppler echocardiography made prior to inclusion.

Neuromuscular disorders  
COPD-Exacerbations during last 4 weeks

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	30
Type:	Actual

## Ethics review

Approved WMO	
Date:	05-05-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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

CCMO

### ID

NL30766.029.10