The effect of non-invasive ventilation on the systemic inflammatory response to exercise in COPD patients.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23644

Source
NTR

Brief title
N/A

Health condition

Chronic obstructive pulmonary disease
Chronisch obstructief longlijden, chronische bronchitis, longemfyseem

Sponsors and support

Primary sponsor: JDC Hannink
Source(s) of monetary or material Support: JDC Hannink

Intervention

Outcome measures

Primary outcome

Systemic inflammatory response.

Secondary outcome

None.

Study description

Background summary

The effect of non-invasive ventilation during exercise on systemic inflammatory responses will be investigated in a double blind randomized placebo controlled (sham ventilation) cross-over design. During the first visit patients will cycle as long as possible, but maximally 20 minutes and during the second visit they will be asked to cycle exactly as long as during the first visit (isotime). Blood will be obtained at rest, at the end of the activity and 30 minutes afterwards to investigate markers of systemic inflammation.

Study objective

Non-invasive ventilation reduces the inflammatory response to exercise.

Study design

1. Rest;

2. After exercise;

3. 30 minutes after exercise.

Intervention

Non-invasive ventilation & sham ventilation.

Contacts

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Eligibility criteria

Inclusion criteria

COPD patients.

Exclusion criteria

1. Long term oxygen therapy;

2. Respiratory insufficiency;

3. Asthma;

4. Exercise limiting disorders;

5. Exacerbation in last 6 weeks;

6. Smoking;

7. Oral corticosteroids;

8. Chronic inflammatory disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-09-2009
Application type:	First submission

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
NTR-new	NL1877
NTR-old	NTR1991
Other	METC Radboud University Nijmegen : 2008/125
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A