EMG measurements of respiratory muscles for the titration of nocturnal non-invasive ventilation in stable chronic obstructive pulmonary disease patients; a randomised cross-over trial.

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Objective: The aim of the present study is to investigate whether additional titration on surface electromyography (EMG) of the diaphragm and intercostal muscles improves outcomes of chronic NIV in patients with COPD and stable CHRF in terms of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON42530

Source
ToetsingOnline

Brief title
Respiratory EMG for NIV titration in stable COPD.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
COPD, longemfyseem

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Obstructive Pulmonary Disease (COPD), non-invasive ventilation, respiratory muscle electromyography

Outcome measures

Primary outcome

Our primary outcome is nocturnal gas exchange after 6 weeks NIV.

Secondary outcome

Secondary outcomes will be better patient comfort, health-realted quality of

life, lung function, and compliance with the ventilator after 6 weeks.

Furthermore, patient-ventilator asynchrony will be assessed.

Study description

Background summary

Rationale:
Long-term application of nocturnal non-invasive ventilation (NIV) in stable hypercapnic chronic obstructive pulmonary disease (COPD) patients has long been controversial as study results were not unequivocal. However, in the past 7 years, with a change in ventilatory strategy, clear benefits of chronic NIV have been shown in COPD patients with chronic hypercapnic respiratory failure (CHRF), though only in stable disease. As a consequence, this so called high-intensity NIV, which is the concept of using higher positive inspiratory airway pressures (IPAP) levels than used in most of the older trials in addition to controlled ventilation with higher backup breathing frequencies aiming for maximal arterial carbon dioxide (PaCO2) reduction, has gained increasing attention.
However, it is unknown how high-intensity NIV works, and how to titrate the optimal IPAP and optimal backup breathing frequency. Measuring respiratory muscle activity might be a way to titrate NIV in COPD.

Study objective

Objective: The aim of the present study is to investigate whether additional titration on surface electromyography (EMG) of the diaphragm and intercostal muscles improves outcomes of chronic NIV in patients with COPD and stable CHRF in terms of better gas exchange after six weeks, lung function, patient comfort and compliance and less patient-ventilator asynchrony (PVA).

Study design

Study design: A randomized, two-armed, crossover trial comparing regular titration with additional respiratory EMG titration of NIV in stable hypercapnic COPD.

Intervention

Intervention: One group will be initiated on NIV according to standard care protocol. For the other group, additional EMG measures whilst on NIV will be made to titrate NIV.

Study burden and risks

There are no risks associated with participation to the study. The study aims to improve the titration of a treatment, NIV, which was already indicated. The EMG measurements used to improve this titration are non-invasive and not associated with any discomfort for the patients. Furthermore, the additional titration of NIV will not go beyond in clinical practice used settings. Most of the measurements are part of daily routine in patients instituted on NIV. Additional measurements done will be a lung function measurement after 6 weeks, which is performed according to guidelines and daily practice, and the comfort and health-related quality of life questionnaires (3 times).

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

- Chronic Obstructive Pulmonary Diseases GOLD stage III or IV (FEV1 < 50% predicted, FEV1/FVC < 70% predicted)
- Indication for the initiation of chronic NIV: PaCO2 > 6.0 kPa at rest during daytime, in stable condition
- Stable COPD (pH < 7,35 and no exacerbation in the past two weeks)
- Age > 18 years

Exclusion criteria

- Respiratory failure of any other cause, for example concomitant neuromuscular disease.
- Already initiated chronic NIV

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2015
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL54678.042.15