Detection of expiratory flow limitation in COPD patients using within-breath forced oscillation technique during CPAP.

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The changes in expiratory flow limitation during increasing levels of external PEEP in COPD patients can be followed with the deltaXrs-8 using FOT.To evaluate whether the deltaXrs is good outcome parameter to determine the external PEEP level needed...

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

Summary

ID

NL-OMON33930

Source
ToetsingOnline

Brief title
FOT and CPAP

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Foreest instituut medisch centrum alkmaar,Philips

Intervention

Keyword: COPD, Expiratory flow limitation (EFL), positive end-expiratory pressure (PEEP), within-breath FOT

Outcome measures

Primary outcome

deltaXrs (cmH20.s/L) at 8 Hz (mid inspiratory minus mid expiratory Xrs) at

increasing levels of PEEP

Secondary outcome

Negative swing inintrapleural pressure at the beginning of the inspiration

measured with an esophageal balloon

Variation in bloodpressure during inspiration and exspiration

spirometry: IC (L)

Xrs-8, 12,16,20,24 (cmH20.s/L) Rrs-8,12,16,20,24 (cmH20.s/L)

Study description

Background summary

Expiratory flow limitation (EFL) is a major determinant of dyspnea and hyperinflation in COPD. Dynamic hyperinflation caused by EFL increases the work of breathing, impairs the function of inspiratory muscles and has adverse effects on hemodynamics. At the end of expiration a positive end-expiratory pressures, intrinsic PEEP, is present. Application of external positive end-expiratory pressure (PEEP) during CPAP (continuous positive airway pressure) may counterbalance the inspiratory threshold load caused by intrinsic PEEP and thereby reducing the work of breathing and the adverse effects on haemodynamics. In a previous study we showed that it is possible to detect EFL with the within-breath forced oscillation technique using maximum overlap discrete Fourier transform and bivariate least squares analysis. The deltaXrs (mid inspiratory minus mid expiratory Xrs) at 8 and 12 Hz is a specific and sensitive tool to detect COPD patients with EFL at rest during normal quiet breathing.

Study objective

The changes in expiratory flow limitation during increasing levels of external PEEP in COPD patients can be followed with the deltaXrs-8 using FOT.
To evaluate whether the deltaXrs is good outcome parameter to determine the external PEEP level needed to counterbalance the intrinsic PEEP without causing further hyperinflation.

Study design

Interventional research.

Intervention

CPAP at different levels of presure (0, 4, 6, 8,10 cmH2O)

Study burden and risks

Participating in this study is low risk. All pulmonary function tests are executed conform the ERS standards. Expected benefit can be improved diagnostics of their pulmonary disease and new insights in the treatment of EFL in COPD patients in the future.

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

Presenting to the outpatient clinic
Age 50-80 years
Diagnosed with COPD according to the standard criteria
Gold Stage II or IV COPD
Current or ex-smokers (at least 10 PY)
Stable disease (No current exacerbation or exacerbation during the 4 weeks previous to the inclusion)

Exclusion criteria

History of exacerbation of COPD in the preceding month
Upper airway obstruction
Allergic Asthma
OSAS (obstructive sleep apnea syndrome)
Extreme obesity (BMI>30)
Pulmonary disease other than COPD
Clinically manifest cardiac disease (for example clinically relevant congestive heart failure, unstable angina pectoris)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2009
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	CPAP
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-04-2009
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	ID
CCMO	NL24161.094.08