inspiratory lung function parameters in subjects with a stable COPD

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With intervention with bronchodilators (usual care bronchodilators for COPD subjects), in one study histamine and in one study steroids, we want to investigate the respons on inspiratory lung function parameter like the FIV1 and also investigate...

Ethical review	Approved WMO
Status	Pending
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON29932

Source
ToetsingOnline

Brief title
Inspiration project 2006.

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
COPD

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: vrijwillige bijdrage voor wetenschappelijke doeleinden

Intervention

Keyword: COPD, FIV1, inspiratory lung function parameters, VAS

Outcome measures

Primary outcome

FIV1

Secondary outcome

IC

Study description

Background summary

The correlation between de intensity of dyspnea and the expiratory pulmonary lung function parameters, for instance the FEV1, in subjects with a stable COPD, is poor. According to Taube et al, AMJRCCM 2000 vol 162 p 216-220, the correlation between the inspiratory lung function parameter FIV1 is better.

Study objective

With intervention with bronchodilators (usual care bronchodilators for COPD subjects), in one study histamine and in one study steroids, we want to investigate the respons on inspiratory lung function parameter like the FIV1 and also investigate with the VAS score what the respons is on the intensity of dyspnea.

Study design

The investigation is done in subjects with a stable COPD. It is a double-blind randomised study (see protocols 1A -1E)
For study 1A the subjects have to come on 3 different days(within 2 weeks) at the policlinic for lung function performance. A long function performance last, with usual care COPD bronchodilator, 30 minutes up to a maximum of 1 hour.
Study 1A-1D last maximum for 1 hour.
For study 1e subject have to visit the us for 7 different days en perform each time lung function which can last for a maximum of 2 hour.

Intervention

All studies are done in subjects witha stable COPD. The main parameter for investigation is FIV1.
study 1A is done with with only once usual care Copd bronchodilators (atrovent aerosol, ventolin aerosol en placebo aerosol), each on three different days.
Study 1B is done with only once inhalation of histamine (ERS criteria)
Study 1C is the effect of pursed lips breathing on the inspiratory lung function parameters.
Study 1D is the done with once inhalation of Combivent via aerosol or with a jet inhaler device
Study 1E is short term effect of corticosteroid, serevent and spiriva on the inspiratory lung function parameter

Study burden and risks

low risk

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

subjects with a stable COPD, mentally normal and with age between 40 end 75 years.

Exclusion criteria

heart diseases, subjects who used systemic corticosteroids less than 2 months ago, diseases which interfere with pulmonary lung function. Astma. Age < 40 years or > 75 years, mentally ill subjects. Subjects with pulmonary malignancy or neuromusculair diseases.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-04-2006
Enrollment:	240
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	atrovent
Generic name:	ipratropium

Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	corticosteroid
Generic name:	prednison
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	salbutamol
Generic name:	ventolin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	serevent
Generic name:	salmeterol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	spiriva
Generic name:	tiotropium
Registration:	Yes - NL intended use

Ethics review

Approved WMO	
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
EudraCT	EUCTR2006-001908-37-NL
CCMO	NL11858.091.06