Active smoking and bronchodilator treatment in patients with chronic obstructive pulmonary disease (COPD): a hazardous combination in causing cardiovascular disease?

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON33894

Source
ToetsingOnline

Brief title
Interaction in COPD Experiment (ICE)

Condition

- Cardiac disorders, signs and symptoms NEC
- Bronchial disorders (excl neoplasms)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cardiovascular disease, emphysema, heart disease. chronic obstructive pulmonary disease

Research involving

Human

Sponsors and support

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

Intervention

Keyword: bronchodilators, cardiovascular disease, COPD, smoking

Outcome measures

Primary outcome

1. The fraction of cigarette smoke particles and constituents retained in the

lungs related to the (changed) lungfunction.

2. The concentration of certain biomarkers associated with cardiovascular

dysfunction and risk, related to the (changed) lungfunction.

Secondary outcome

not applicable

Study description

Background summary

COPD currently is one of the most frequent diseases. In more than 90% of COPD patients, the disease is caused by smoking. About half of the COPD patients are active smokers, although smoking is also the most important prognostic factor. Also, smoking is an important cause as well as an important prognostic factor in cardiovascular disease. The corner stone of medical treatment in COPD is bronchodilation; more than half of the patients use a long-acting bronchodilator. Recently, several studies suspect a possible relation between these long-acting agents and cardiovascular disease. Surprising however, no studies are done to investigate the interaction between the most important prognostic factor (smoking) and the most important treatment (bronchodilation). An increase of the pathogenic effect of smoking by an increased longfunction after bronchodilation is likely though, since more pathogenic particles would penetrate the lung parenchym. This mechanism would thereby negatively affect

smoking-related morbidity, especially cardiovascular disease. Therefore, our hypothesis is that long-acting bronchodilators increase cardiovascular disease in COPD patients who smoke.

Study objective

The aim of the study is to demonstrate a basic mechanism that supports our hypothesis: Does increased respiratory function after administration of a bronchodilator in patients with COPD lead to elevated pulmonary retention of the harmful compounds in inhaled cigarette smoke and to short-term biological effects associated with cardiovascular disease?

Study design

A randomised doubleblinde crossover intervention study of a cohort in a laboratory setting.

Intervention

Patients recieve whether a bronchodilator or a placebo twice, preceded and followed by repeatedly inhaling cigarette smoke during two hours as by a strict time schedule.

Study burden and risks

The interventions of the experiment do not essentially differ from the home situation. The burden of the experiment is mainly based on spended time of the patient and possibly on an experienced nuisance by the venapuncture. Venapuncture is a wide accepted and applied action. The risk is reasonably neglectable since it is only caused by the relative harmless risks of venapuncture, that may cause a hematoma or slight bleeding.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101

6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

active cigarette smoker
COPD gold klasse II-III

Exclusion criteria

not mastering the Dutch language
not capable of following technical instructions
not willing to withheld from smoking and bronchodilation for a certain time before the study
recent exacerbation within the last 2 weeks before the experiment
asthmatic component

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2009
Enrollment:	50
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	20-05-2009
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
CCMO	NL25227.091.09