Airflow Limitation in Cardiac Diseases in Europe (the ALICE study).

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

Summary

ID

NL-OMON35465

Source
ToetsingOnline

Brief title
ALICE

Condition

- Cardiac disorders, signs and symptoms NEC
- Respiratory disorders NEC

Synonym
COPD, Ischemic Heart Disease

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: GlaxoSmithKline BV

Intervention

Keyword: Airflow Limitation, cardiac diseases, COPD, prevalence

Outcome measures

Primary outcome

Airflow Limitation, defined by FEV1/Forced Volume Capacity (FVC) < 0.70 (post bronchodilator), and measured by standardised spirometry equipment.

Secondary outcome

• Severity of airflow limitation, as defined by GOLD stages

• Restrictive airflow limitation, defined by FEV1/FVC >=0.70 and a predicted FVC <80% (pre bronchodilator)

• Airflow limitation as defined by FEV1 below the lower limit of normal (LLN), as measured by standardised spirometry equipment;

• Presence of past history of airflow limitation or COPD;

• Health status questionnaire scores (COPD Assessment test* (CAT), SF12, Cardiac Health Profile);

• Healthcare utilisation: Number of emergency room visits and hospital admissions in previous 12 months.

Study description

Background summary

Airflow limitation (AL) occurs in a number of respiratory diseases including asthma and COPD; in middle-aged and older patients it typically represents COPD, and is associated with a high degree of co-morbidity which includes cardiovascular diseases and risk factors such as hypertension and diabetes.

Chronic Obstructive Pulmonary Disease (COPD) is mainly related causally to

smoking and ageing. The prevalence estimates in the general adult population are influenced by sampling methodologies and by methods used to identify COPD, and underlying prevalence of risk factors that vary geographically. In reports from studies of those aged 40 years or older, prevalence ranges from 4% to more than 20% [Buist, 2007;
Menezes, 2005].

COPD often goes undiagnosed, especially in patients with established coronary disease because COPD and cardiovascular diseases share a major etiological factor: smoking. The WHO estimated that in 2000, 4.83 million premature deaths in the world were attributable to smoking, the three leading causes of death from smoking being CVD (1.69 million deaths), COPD (0.97 million deaths), and lung cancer (0.85 million deaths) [Ezzati, 2003].

The association of COPD with increased morbidity, hospital admissions, worse health status, increased inflammatory markers and cardiovascular disease has been documented [Melbye, 2007; Sin, 2005]. Individuals with reduced lung function have an increased risk
of cardiovascular disease which is independent of smoking [Sin, 2005], and therefore establishing the prevalence of COPD in cardiovascular patients will be important in identifying patients at risk.

The prevalence of cardiovascular conditions and other co-morbidities in COPD patients, with a range of severities, has been reported extensively before for example: [Soriano, 2005; Hansell, 2004; Rodríguez-Roisin, 2008]. On the other hand, the prevalence of AL and/or COPD has yet to be fully determined in patients with established cardiovascular disease.

One of the first studies to prospectively investigate the prevalence, severity and treatment of COPD in patients with established cardiovascular disease (CVD) concluded that 34% (95% confidence interval (CI): 25-42) of Spanish CVD patients (one in three patients with coronary artery disease recruited from a hospital clinic, and one in five patients with CVD in the general population) suffered airflow limitation compatible with COPD [Soriano, 2010]. Importantly, the majority of patients with coronary artery disease and AL (87.2%) were not diagnosed for their AL, and remained mostly untreated.

Additionally, studies from Japan have examined the prevalence of COPD in various comorbid populations [Yamasaki, 2010; Fukahori, 2009]; and of particular interest, [Wada, 2010], examined 753 patients attending a cardiovascular outpatient clinic and identified 79 (10.5%) as COPD (FEV1/FEV6 <0.70) with the PiKo-6. However, [Izquierdo, 2010], concluded that COPD was not associated with Ischemic Heart Disease (IHD), and that the greater prevalence of classical CV risk factors in COPD patients could explain the higher occurrence of IHD in these patients.

Establishing the prevalence of AL in cardiovascular patients, and describing

the burden of these diseases, especially in those patients with undiagnosed AL, will provide evidence supporting a pro-active approach for identification of COPD among patients with established cardiac disease.

Study objective

The primary objective is to establish the point prevalence of Airflow Limitation (AL) compatible with COPD, in current/former smokers, with established cardiac diseases, in Europe.

Secondary Objectives are:
• To establish the point prevalence of AL compatible with COPD stratified by the major population characteristics;
• To establish the overall burden of AL in patients with cardiac diseases, stratified by cardiac disease type (IHD only, co-morbid Congestive Heart Failure (CHF) or comorbid with other cardiac diseases (other than CHF)):
• To compare health status in patients with cardiac diseases with and without AL, and with or without prior COPD diagnosis (see Section 4.3, for definition),
• To compare healthcare resource utilisation in patients with cardiac diseases with and without AL, and with or without prior COPD diagnosis;
• To explore the relationship between cardiac disease and risk factors with AL:
• To explore whether the type of cardiac disease diagnosis (IHD only, co-morbid CHF, or co-morbid with other CV disease (other than CHF)) is related to the presence and severity of AL, after adjustment for other risk factors of AL (e.g. smoking),
• To explore whether the presence of airflow limitation is related to the severity of cardiac disease;

Study design

A cross-sectional, observational cohort study.

Study burden and risks

Burden and risks are small.
There is no investigational product in this study, hence no adverse events are to be expected in this regard.
Drawing a bloodsample can be painful and leave a bruise.
Measuring spirometry may lead to difficulty in breathing.
The brochodilator that will be adminisered during spirometry (Ventolin) will have a small chance of temporary adverse events.

Participants only have 1 study visit, and no behavioural rules are imposed on them.

There is a possible benefit if and when subjects are diagnosed with untreated

COPD. Referral, diagnosis and treatment may lead to a better health status.

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

1. Subjects aged >=40 years;
2. Current or former smokers with >=10 pack years;
3. Subjects attending outpatient cardiac clinic (or equivalent) fulfilling any of the following criteria:
a. Documented history of an Ischemic event,
b. Current diagnosis of stable IHD (including history of acute Myocardial Infarction'(MI) and angina pectoris) as diagnosed in accordance with ESC guidelines
c. Receiving regular therapy for IHD for >1yr,

4. Subjects willing and able to sign study consent form.

Exclusion criteria

1. Subjects for whom spirometry is contraindicated (e.g. with detached retina, active tuberculosis, last trimester of pregnancy, resting pulse >120 etc);
2. Subjects with recent surgery or MI (within 1 month); lower respiratory tract infection or pneumothorax (within 2 months); or stroke (within 12 months);
3. Subjects with a pre-existing condition which, in the opinion of the investigator, would compromise the safety of the subject in this study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	04-10-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-10-2011

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL37750.060.11
Other	nog niet bekend, wordt via openbare database op http://www.gsk-clinicalstudyregister.com/ geregistreerd