Assessment of Comorbidities in COPD in European Symptomatic Subjects from primary care.

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The primary objective of this study is:• To compare the rate of moderate-severe COPD exacerbations in COPD patients with and without cardiovascular diseases (CVD) The secondary objectives are:• To compare the rate of moderate-severe COPD...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON39121

Source
ToetsingOnline

Brief title
ACCESS

Condition

- Respiratory disorders NEC

Synonym
COPD, lung emphysema

Research involving
Human

Sponsors and support

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

Intervention

Keyword: co-morbidities, COPD

Outcome measures

Primary outcome

• Rate of COPD exacerbations (moderate-severe severity), based on a healthcare utilisation defined as a worsening of symptoms that require oral corticosteroids and/or antibiotics and/or hospitalizations

• Presence and severity of pre-defined cardiovascular diseases

Secondary outcome

• Presence and severity of other treated comorbidities

• Spirometry measurements - FEV1, forced vital capacity (FVC), FEV1/FVC ratio

• Health status scores - CAT; EQ-5D; Hospital Anxiety and Depression Scale (HADS); Epworth Sleepiness Scale (ESS); Frequency Scale for the Symptoms of Gastro-oesophageal reflux disease (FSSG)

• Medical Research Council (MRC) scores

• Number of deaths

• Healthcare utilisation: number of unscheduled GP contacts and hospitalisations

• Blood chemistry, including glucose; Haemoglobin A1C (HbA1c);; low density lipoprotein (LDL-c), High density lipoprotein (HDL-c), Total cholesterol; triglycerides, prohormone natiuretice peptide (pro-BNP); high-sensitivity C reactive protein (hs-CRP); protein; full blood count

• Blood pressure and electrocardiogram (ECG)

• Number of bone fractures

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide. Comorbid diseases are an important factor in the prognosis and functional capabilities of COPD patients. There is a relationship between cardiac comorbidity and COPD exacerbation frequency within COPD patients and it has been observed that patients with a higher COPD exacerbation frequency have a higher risk of cardiac events. A greater understanding of comorbidities, their prevalence, severity, management and incidence over time in a primary care COPD population; as well as correlation with COPD exacerbations, forced expiratory volume in 1 second (FEV1) and health-related quality of life (HRQL), can inform on optimal management of COPD in general practice.

Study objective

The primary objective of this study is:
• To compare the rate of moderate-severe COPD exacerbations in COPD patients with and without cardiovascular diseases (CVD)

The secondary objectives are:
• To compare the rate of moderate-severe COPD exacerbations in COPD patients with and without other defined comorbidities
• To characterize the prevalence, severity and incidence over time of comorbidities in a primary care COPD population
• To evaluate the relationship between CVD/other comorbidities and FEV1 decline
• To evaluate the relationship between CVD/other comorbidities and EQ-5D
• To evaluate the relationship between CVD/other comorbidities and COPD Assessment Test* (CAT) scores
• To evaluate the longitudinal properties of the CAT in a primary care setting

An additional objective is:
• To evaluate the relationship between CVD and COPD exacerbations recovery time (time to recover to normal activity)

Study design

A prospective, observational, non-drug interventional, non-randomized study.

Study burden and risks

Burden description:
Patients will have to fill out questionnaires during 4 visits (11 questionnaires in total), they will have 2 bloodsamples taken (ca. 20 mL in total), vital signs measured twice, ECG performed twice, longfunction (incl. reversibility) measured 2-3 times.

Risk assessment:
Small to none. 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.

There is a possible benefit that subjects will have their health status monitored more closely by their general practicioner, who can intervein earlier if necessary if anything is identified.

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. Males/females >= 40 years of age.
2. COPD (all GOLD-stages) diagnosed >= 12 months ago.
3. FEV1/FVC (tiffeneau-index) after use of bronchodilator < 0.70.
4. Smoking history of >= 10 packyears
5. Singed informed consent form.

Exclusion criteria

1.In the opinion of the investigator, there is a current primary diagnosis of asthma (patients with a primary diagnosis of COPD but who also have asthma may be included)
2.A diagnosis of fibrosis or asbestosis
3.Diagnosis of cancer - includes current and within the last 5 years (patients in remission for >= 5 years may be included). Patients diagnosed with cancer during the study will be withdrawn
4.Diagnosis of clinically significant bronchiectasis
5.Subjects who are concurrently participating in any clinical study or who have received any investigational drugs within 4 weeks of Visit 1, or who will start any during the study period.
6.Unable to or unwilling to conform with the study requirements including completion of the health status questionnaires
7.Females who are pregnant or lactating.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2011
Enrollment:	480
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-02-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-04-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-04-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	05-09-2013
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	NL37931.060.11
Other	nog niet bekend, wordt via openbare database op http://www.gsk-clinicalstudyregister.com/ geregistreerd