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Predicting outcome using systemic markers In severe exacerbations of chronic obstructive pulmonary disease

Submission date	Recruitment status	[_] Prospectively registered
15/02/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/03/2018	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
PRedicting Outcome using systemic Markers In Severe Exacerbations of Chronic Obstructive Pulmonary Disease (COPD): the PROMISE-COPD cohort study

Acronym
PROMISE-COPD

Study objectives
Circulating biomarkers might be able to predict exacerbations during the stable state of the disease and the clinical outcome of the exacerbations in patients with chronic obstructive pulmonary disease (COPD). Thus, we aim to:
1. Describe the four-week course of clinical, laboratorial, and lung function parameters during exacerbations of COPD as compared to the stable state of the disease
2. Explore predictors that might identify recurrence and poor outcome in the stable state and during exacerbations
3. Analyse the potential of circulating biomarkers for the diagnosis and prognosis of COPD in the stable state and during exacerbations, including a correlation with the number of hospitalisations and death of any cause
4. Assess whether easily to determine circulating biomarkers are capable to replace the widely accepted BODE (body mass index, airflow obstruction, dyspnea, and exercise capacity) index as predictor of long term prognosis in COPD
5. Analyse the impact of viral and bacterial infections as well as pulmonary embolism on in-hospital and long-term clinical outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Basel (Ethikkommission Beider Basel) (Switzerland), 24/09/2007, ref: EKBB 295/07

Study design
International multicentrre longitudinal closed observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
COPD will be diagnosed according to the GOLD guidelines (forced expiratory volume in one second [FEV1]/forced vital capacity [FVC] ratio below 70% and an absolute reduction of FEV1 below 80% of the predicted value). Acute exacerbation of COPD will be defined as "an event in the natural course of the disease characterised by a change in the patient's baseline dyspnea, cough, and/or sputum that is beyond normal day-to-day variations, is acute in onset, and may warrant a change in regular medication in a patient with underlying COPD".

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Clinical end-points include the following (duration of follow-up: two years):
1. Number of exacerbations, including exacerbations requiring hospitalisation and exacerbations managed by the primary care physicians
2. Number of deaths of any cause
3. Number of respiratory-related deaths
4. Time to next exacerbation, time to next exacerbation requiring hospitalisation and time to death
5. Duration of hospitalisation
6. Admission and length of stay in intensive care unit
7. Need for intubation or non-invasive ventilation
8. Need for oral steroids and antibiotics
9. Lung function and 6-minute walk test changes

Secondary outcome measures
1. Quality of life assessed by Saint Georges Respiratory Questionnaire and the 36-item Short Form Health Survey (SF-36) at every scheduled visits during the follow-up phase (every 6 months) and 4 weeks after an exacerbation
2. Dyspnea and respiratory symptoms as assessed by the Modified Medical Research Council (MMRC) scale and Lower Respiratory Tract Illness - Visual Analogue Scale (LRTI-VAS) at every scheduled visits during the follow-up phase (every 6 months) and 4 weeks after an exacerbation

Added 27/10/2010:
3. Measurement of daily physicial activity as assessed by a triaxial accelerometer at stable phase of the disease and exacerbation

Overall study start date
01/01/2008

Completion date

31/12/2012

Eligibility

Key inclusion criteria
1. Age above 40 years, both men and women
2. Smoking history greater than or equal to 10 pack years
3. Moderate to very severe COPD (Global Initiative for chronic Obstructive Lung Disease [GOLD] II to IV)
4. Currently stable disease (at least 4 weeks after resolution of the last exacerbation)
5. Willingness to participate in a longitudinal, cohort study
6. Willingness of the family physician to have the patient included in a cohort study
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Rapid fatal disease
2. Pulmonary condition other than COPD as the main respiratory disease, e.g. bronchiectasis, asthma or pulmonary fibrosis
3. Immunosuppression including human immunodeficiency virus (HIV), organ transplantation or chronic steroid use (more than 10 mg prednisolone-equivalent per day)
4. Patients unable and unwilling to give written informed consent
5. Musculoskeletal process preventing ambulation

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Belgium

Germany

Greece

Italy

Netherlands

Serbia

Spain

Switzerland

Study participating centre
University Hospital Basel
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital Basel (Switzerland)

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Sponsor type
Hospital/treatment centre

Website
http://www.dfbs.ch

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/12/2015		Yes	No
Results article	results	21/03/2018		Yes	No