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The prevalence and significance of chronic obstructive pulmonary disease in subjects with acute coronary syndrome

Submission date
20/03/2012

Recruitment status
No longer recruiting

Registration date
04/05/2012

Overall study status
Completed

Last Edited
14/02/2017

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a group of lung conditions that cause breathing difficulties. COPD shares a common risk factor, tobacco, with heart disease, which is currently the leading cause of death globally. Studies have found that patients with COPD have an increased risk of heart disease. However, these studies have several limitations. Firstly, the diagnosis of COPD has been based purely on medical records. Secondly, patients with asthma have sometimes also been included. As about 80% of patients with COPD are undiagnosed and 20-50% of patients with COPD do not fulfil the diagnostic criteria, the prevalence of COPD in heart disease has not been reliably assessed. Spirometry is a simple test that can be used to diagnose COPD by measuring how much air patients can breathe out in one forced breath. The aims of this study are to estimate the true prevalence of COPD in heart disease using spirometry, and to find out whether spirometry-verified COPD predicts heart disease prognosis.

Who can participate?
Patients hospitalised with heart disease (myocardial infarction or unstable angina), living in the county of Jämtland, Sweden

What does the study involve?
Participants' lung volumes are measured (spirometry) during hospitalisation or at the first follow-up outpatient visit after discharge. The prevalence of spirometry-detected COPD is compared with the prevalence of COPD based on medical records.

What are the possible benefits and risks of participating?
If COPD is detected, participants receive disease information and, if needed, are offered treatment. The test requires forced expirations (breathing out). Some may experience slight physical discomfort during the test.

Where is the study run from?
Östersund Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2010 to December 2014

Who is funding the study?
1. Jämtland County Council (Sweden)
2. The Swedish Heart and Lung Association (Sweden)

Who is the main contact?
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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
The prevalence and significance of Chronic Obstructive Pulmonary disease in subjects with Acute Coronary Syndrome: an observational study

Acronym
COPACS

Study objectives
1. Spirometry screening after acute coronary syndrom (ACS) will reveal that the majority of subjects with chronic obstructive pulmonary disease (COPD) are undiagnosed.
2. Spirometry-verified COPD is an independent predictor of death, reinfarction and stroke in subjects with Acute Coronary Syndrome (ACS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board, Umeå University, Umeå, Sweden, 16/12/2009, ref: Dnr 09-142M

Study design
Single-centre observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

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, acute coronary syndrome

Interventions
The study subjects will be screened with spirometry to detect presence of chronic airflow limitation. Lung volume measurements (spirometry) will be done during the hospitalisation or at the first follow-up out-patient visit after discharge. Vital capacity (VC), forced vital capacity (FVC) and forced expiratory volume in one second (FEV1) will be measured before and after bronchodilation. FEV1/FVC <0.7 post bronchodilation will be considered as COPD.

The prevalence of spirometry-detected COPD will be compared with the prevalence of COPD based on medical records in the study population. We will evaluate whether spirometry-verified COPD predicts prognosis after ACS. Inclusion between 01 January 2010 and 30 June 2012, follow-up until 31 December 2014.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The prevalence of spirometry-verified COPD versus medical-record based COPD in subjects with ACS
2. The adjusted hazard ratio of spirometry-verified COPD for death, reinfarction and stroke in subjects with ACS. Adjustment for age, gender, renal function, C-reactive protein, Killip class, previous myocardial infarction (MI), atrial fibrillation, coronary intervention, secondary preventive medication, diabetes, and smoking history.

Secondary outcome measures
In subjects with ACS, spirometry-verified COPD is an independent predictor of hospital admissions (due to coronary angiography, percutaneous coronary intervention, coronary artery bypass surgery, angina, heart failure) and length of hospital stay.

Overall study start date
01/01/2010

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. All patients living in the county of Jämtland, Sweden, and hospitalised with a diagnosis of myocardial infarction or unstable angina will be assessed for inclusion
2. Östersund hospital is the only hospital in the county and all patients, terminal care excluded, with symptoms of a suspected acute coronary syndrome are referred for diagnostic evaluation
3. Study subjects are recruited in conjunction with the study "Secondary preventive, nurse based, telephone follow-up for risk factor control after an acute coronary syndrome" (http://www.isrctn.com/ISRCTN96595458/)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
350 subjects

Key exclusion criteria
1. Dementia
2. Patients with severe disease
3. Subjects unable to perform adequate spirometry

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Sweden

Study participating centre
Jamtland County Council
Östersund
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Sponsor information

Organisation
Jämtland County Council (Sweden)

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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Jämtland County Council (Sweden)

Funder Name
Hjärt-Lungfonden

Alternative Name(s)
Swedish Heart-Lung Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

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	01/08/2015		Yes	No