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Validation of prognostic indices ADO, BODEx and DOSE in a primary care international cohort (cohort PROEPOC/PROCOPD)

Submission date
15/01/2015

Recruitment status
No longer recruiting

Registration date
05/02/2015

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Respiratory

[X] 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 the name used to refer to a number of progressive devastating and debilitating lung diseases, which includes chronic bronchitis, emphysema and chronic obstructive airways disease. People that have COPD typically feel breathless after physical activity, have a persistent cough with phlegm and suffer frequently from chest infections. There is no cure for the condition, but making lifestyle changes (such as stopping smoking) and taking medications (inhalers and/or tablets) can alleviate symptoms. Pulmonary rehabilitation, a programme of physical exercise and education, can also help people manage their condition and lead to improvements in health. The main aim of this study is to improve the overall assessment of patients with COPD. To do this, the available diagnostic assessments will be compared using carious scales. The results will be analysed and recommendations made on which of these are the most suitable for use in primary care (for example, GP surgeries).

Who can participate?
Adults diagnosed with COPD.

What does the study involve?
Clinical information about each participants COPD and their treatment is collected. Laboratory analysis, chest x-ray and electrocardiogram (EKG) may be performed, depending on the stage of diagnosis. If a participant has not had a spirometry (a test to diagnose lung disease) at some point in the last 6 months a new one is performed. The study is carried out at the participants health centre and they are followed for five years with the data is obtained by reviewing medical records or by interview (face to face or telephone).

What are the possible benefits and risks of participating?
Participants do not get any direct benefit from participating but they are given a summary of the study results and results of their tests if they wish. The completion of the questionnaires and tests to be performed do not involve any harm health or affect treatment.

Where is the study run from?
Primary Care Centres from Vigo (Galicia), Balearic Islands, Aragón, Catalonia, and Canary Islands in Spain, and from Bulgaria, Croatia, Germany, Macedonia, Romania and Slovenia in Europe.

When is the study starting and how long is it expected to run for?
January 2015 to December 2020

Who is funding the study?
Spanish Ministry of Economy (Spain), European General Practice Research Network

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Spanish Ministry of Economy, Instituto de Salud Carlos III, code PI14/00385.

Study information

Scientific Title
COPD patients prognosis with multicomponent scales (ADO, BODEx) in primary care: scale validation study, open, multicenter and prospective

Acronym
PROCOPD/PROEPOC

Study objectives

1. Main hypothesis 1:
The ADO and BODEx indices, validated predominantly in cohorts from hospital settings, can have a different prognostic capacity in a PC setting, due to the differences in severity and other clinical and social characteristics that depend on the setting in which patients are treated. Therefore, we need to verify if the capacity of these indices to discriminate and calibrate patients is maintained when they are applied in primary care.
2. Main hypothesis 2:
The ADO, BODEx and DOSE indices, obtained in the PC setting, can show a different prognostic capacity in each subgroup, according to the GOLD classification and for each phenotype according to the GesEPOC classification. We hope that the prognostic capacity is better in groups C and D of the GOLD classification and in the exacerbator phenotypes of the GesEPOC, because these patients may be more widely represented in the population treated in the hospital and have lower intragroup variability. The prognostic capacity for the GOLD subgroups will vary according to whether CAT or MRC is used for their classification.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Galician Ethics Committee (Spain), 06/02/2013, ref: 2010/310

Study design
Open prospective and multi-centre validating scales study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
Those patients who are diagnosed with COPD and cared for by participating general practitioners will be included, provided that they fulfil the inclusion criteria. The healthcare professionals will identify potentially eligible cases, within their quota of assigned patients, through electronic medical records and will select a random sample of them (10 per professional). Patients will be included in the study if they have already been correctly diagnosed with COPD. The results of a test taken in the last six months during a stable phase will be considered valid; if the last test was more than 6 months ago, a new spirometry test will have to be taken. A forced spirometry test is required, for which the recommendations of the Spanish Society for Pneumology and Thoracic Surgery (SEPAR) and/or will be followed (34). Once a diagnosis is established, the severity of the obstruction is classified in relation to the post-bronchodilator FEV1 value, expressed as a percentage of the expected level. The undertaking of the spirometry test and its interpretation will be the responsibility of specially trained staff, who has taken an accredited and tutored theoretical and practical course.

Intervention Type
Mixed

Primary outcome(s)
Survival without exacerbations will be assessed after 3, 4 and 5 years.

Key secondary outcome(s))
Mortality from all causes and those specifically due to respiratory causes (secondary)

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/01/2016:
Setting: Primary Care Centres in Teis, Matamá, Pazos de Borbén and Sárdoma in the Vigo Health Authority (Pontevedra, Galicia), and Son Pisà, Escola Graduada and Coll dén Rebassa in the Balearic Islands Health Authority (Balearic Islands). Through these centres, doctors/nurses potentially willing to participate were identified (using the 'snowball' method) both in Spain (Aragón, Catalonia, Canary Islands) and other European countries (Bulgaria, Croatia, Germany, Macedonia, Romania and Slovenia, in Europe).

Subjects: Patients diagnosed with COPD.
Inclusion criteria:
1. Patients with an obstruction, defined by a FEV1 lower than 80% of the expected post-bronchodilator FEV in the presence of a FEV1 quotient/forced vital capacity (FVC) lower than 70%.
2. Patients in a stable phase of COPD, clinically defined as at least 6 weeks since the last exacerbation
3. Acceptance to participate in the study by providing written informed consent

Previous inclusion criteria:
Setting: Primary Care Centres in Teis, Matamá, Pazos de Borbén and Sárdoma in the Vigo Health Authority (Pontevedra, Galicia), and Son Pisà, Escola Graduada and Coll dén Rebassa in the Balearic Islands Health Authority (Balearic Islands). Through these centres, doctors/nurses potentially willing to participate will be identified (using the 'snowball' method) both in Spain and other European countries to be confirmed.
Subsequently, they will be invited and informed by e-mail about the description of the background and objectives of the study, as well as the implications of their participation.

Subjects: Patients diagnosed with COPD.
Inclusion criteria:
1. Patients with an obstruction, defined by a FEV1 lower than 80% of the expected post-bronchodilator FEV in the presence of a FEV1 quotient/forced vital capacity (FVC) lower than 70%.
2. Patients in a stable phase of COPD, clinically defined as at least 6 weeks since the last exacerbation
3. Acceptance to participate in the study by providing written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
COPD patients.
Exclusion criteria:
1. Patients diagnosed with cystic fibrosis, or bronchiectasis of a different origin to COPD (tuberculosis, childhood infections, immunodeficiencies, and severe cognitive or mobility impairment).
2. Patients diagnosed with a severe chronic disease, besides COPD (active malignancy, AIDS, heart failure, severe kidney or liver failure, etc.)

Date of first enrolment
10/02/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Bulgaria

Croatia

Germany

North Macedonia

Romania

Slovenia

Spain

Study participating centre
EOXI Vigo, Galician Health Service
Rosalía Castro 21, 7°
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Study participating centre
Primary Care Majorca Department, Son Pisà Primary Health Centre
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Sponsor information

Organisation
Instituto de Salud Carlos III (Spain)

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
Spanish Ministry of Economy, Instituto de Salud Carlos III

Funder Name
European General Practice Research Network

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/11/2016	26/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes