

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

<b>Submission date</b> 15/01/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2022	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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 various 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 participant's 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 participant's health centre and they are followed for five years with the data 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?

Dr Ana Clavería

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

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

## **Secondary study design**

Cohort study

## **Study setting(s)**

GP practice

## **Study type(s)**

Diagnostic

## **Participant information sheet**

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

## **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 measure**

Survival without exacerbations will be assessed after 3, 4 and 5 years.

## **Secondary outcome measures**

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

## **Overall study start date**

01/01/2014

## **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 d'en 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 d'en 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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

477

### **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, 7º

Vigo, Galicia

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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)

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.isciii.es/ISCIII/es/general/index.shtml>

**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

## Publication and dissemination plan

Study protocol to be published in BMC Family Practice

Basal data in next year. Final data in five years.

## Intention to publish date

15/02/2015

## 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?
<a href="#">Results article</a>		11/11/2016	26/10/2022	Yes	No