Multi-component assessment systems and predicting future risk in chronic obstructive pulmonary disease

First published: 10/06/2014

Last updated: 14/08/2014

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/7250

EU PAS number

EUPAS6749

Study ID

7250

DARWIN EU® study

No

Study countries

☐ Netherlands

Sweden

United Kingdom

Study description

A study to evaluate the Dyspnoea, Obstruction, Smoking, Exacerbation (DOSE) and the Age, Dyspnoea, Obstruction (ADO) indices and GOLD categories as measures of current health status and future outcomes in COPD patients using observational cohort studies comprising 5116 primary care COPD patients across three databases from UK, Sweden and Holland.

Study status

Finalised

Research institutions and networks

Institutions

International Primary Care Respiratory Group (IPCRG)

United Kingdom

First published: 10/06/2014

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Institution | Not-for-profit

Leiden University Medical Centre (LUMC)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Uppsala University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Peninsula College of Medicine and Dentistry, Plymouth University United Kingdom, Department of Public Health and Primary Care, Leiden University Medical Center Netherlands, Department of Public Health and Caring Sciences, Family Medicine and Preventive Medicine, Uppsala University Sweden

Networks

Respiratory Effectiveness Group (REG)

- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

First published: 07/07/2021

Last updated: 04/06/2024

Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rupert Jones

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/02/2012

Actual: 24/02/2012

Study start date
Planned: 30/03/2012

Actual: 30/03/2012

Date of final study report
Planned: 10/06/2014

Actual: 10/06/2014

Sources of funding

- Non-for-profit organisation (e.g. charity)
- Other

More details on funding

IPCRG, REG

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the Dyspnoea, Obstruction, Smoking, Exacerbation (DOSE) and the Age, Dyspnoea, Obstruction (ADO) indices and GOLD categories as measures of current health status and future outcomes in COPD patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Primary care COPD patients

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

5116

Study design details

Outcomes

DOSE and ADO associations with health status measured by the CCQ and SGRQ, Current symptoms, exacerbations and hospital admissions, Future events of exacerbations, admissions and mortality, Distribution of GOLD categories according to different methods of calculation

Data analysis plan

Spearmans rank correlation was used to assess the association between each of the DOSE and ADO indices and the health status measures and markers of

healthcare consumption in each of the 3 datasets. Logistic regression analysis was used to calculate the unadjusted odds ratio for 1 or more hospital admissions and for 1 or more exacerbations in the subsequent year for a unit increase in the DOSE or ADO indices. ROC analyses and AUC were produced for DOSE and ADO indices in relation to the prediction of future risk of exacerbations and admissions. Negative binomial regression models and Cox regression were also used.

Data management

Data sources

Data source(s), other

Optimum Patient Care (OPCRD) United Kingdom, PRAXIS-study Sweden, Bocholtz study Netherlands

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No