Long-term outcomes and adverse events of therapy with inhaled corticosteroids, long-acting beta-2-agonists and anticholinergic drugs in hospitalised patients with Chronic Obstructive Pulmonary Disease (COPD) - a cohort study based on health information systems in three Italian regions (OUTPUL)

First published: 27/10/2010

Last updated: 30/03/2015

Study Finalised

Administrative details

EU PAS number

EUPAS1578

Study ID

9133

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Objectives: to measure long-term outcomes and adverse events of inhaled drugs in COPD patients, to compare effectiveness of the different drugs (mono- and polytherapy) in terms of long-term survival or exacerbations, to compare incidence of side effects of inhaled therapy among users vs non-users. Design: patients discharged with COPD in 2006-07 will be enrolled from the Hospital Information Systems (HIS) and record linkage performed with mortality, hospital, emergency and drug claims data to define exposure (ICS, LABA, and anticholinergics), potential confounders, and to measure outcomes over 4 years. Outcomes: all-cause, respiratory and cardiovascular mortality, incidence of adverse events, and COPD exacerbations. Cox-proportional-hazard models will be applied to compare outcomes in users vs non-users of exposure to different drug groups (mono-/polytherapy). Sensitivity analyses will take into account different subgroup susceptibility or different definitions of chronic exposure.

Study status

Finalised

Research institutions and networks

Institutions

Department of Epidemiology of the Regional Health Service - Lazio

Italy

First published: 23/03/2010

Last updated: 22/06/2018

Institution | Outdated | EU Institution/Body/Agency | ENCePP partner

Emilia-Romagna Health and Social Agency (ASSR Emilia-Romagna)

Italy

First published: 23/04/2010

Last updated: 18/12/2017

Institution | Outdated | Laboratory/Research/Testing facility | ENCePP partner

Epidemiologic Observatory of the Health Directorate of the Lombardy region, Milan, Italy, Respiratory Physiology Unit in the Columbus Hospital, Catholic University, Rome, Italy

Contact details

Study institution contact

Nera Agabiti u.kirchmayer@deplazio.it

Study contact

u.kirchmayer@deplazio.it

Primary lead investigator

Nera Agabiti

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2010

Actual: 16/06/2010

Study start date

Planned: 15/09/2010

Actual: 15/09/2010

Data analysis start date

Planned: 01/01/2012

Actual: 02/01/2012

Date of interim report, if expected

Planned: 31/12/2011

Actual: 31/12/2011

Date of final study report

Planned: 01/06/2013

Actual: 01/06/2014

Sources of funding

- Other

More details on funding

AIFA (Italian Medicines Agency), Participating centres

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To measure long-term outcomes and adverse events of inhaled drugs in the study cohort over a 4-year follow up period, to compare effectiveness of the different drugs (both “monotherapy” and “combined therapy”) in terms of long-term survival or exacerbations, to compare the incidence of side effects of inhaled therapy (ICS, LABA and anticholinergics) among users versus non users.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03) DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

(H02AB) Glucocorticoids

Glucocorticoids

(J01) ANTIBACTERIALS FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Patients aged > 45years and resident in the study areas with acute exacerbation of COPD during a two-year period (2006-07)

Age groups

- 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

40000

Study design details

Outcomes

Mortality (All causes, respiratory causes, cardiovascular causes), COPD exacerbation defined as either a hospital admission/emergency visit for COPD or COPD-related causes or a prescription for an oral corticosteroids with/without systemic antibiotic, Adverse cardio- and cerebrovascular events, Pneumonia, Osteoporotic fractures

---

Data analysis plan

Cox proportional hazard models will be applied to compare outcomes in users vs non-users of exposure to different drug groups (mono-/polytherapy). Sensitivity analyses will take into account different subgroup susceptibility or different definitions of chronic exposure.

Documents

Study publications

Di Martino M1, Agabiti N, Bauleo L, Kirchmayer U, Cascini S, Pistelli R, Colame…

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

This study has been awarded the ENCePP seal

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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