Decline In lung-function Among Patients with chronic obstructive Lung disease On maintenance therapy (DIAPLO)

First published: 14/07/2017

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS19879

Study ID

19880

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Chronic obstructive pulmonary disease (COPD) is a respiratory condition affecting airflow in the lungs, leading to symptoms such as shortness of breath and tightness in the chest. It is not reversible and becomes gradually worse over time. No single drug has been shown to prevent progressive loss of lung function. However, if treated early with a triple combination of inhaled drugs, relevant effects may be achieved. The proposed study aims to explore lung function decline over time, in patients at the early stages of COPD who are receiving various types of treatment. Using several years of anonymous patient information from General Practices, the study will initially assess an existing tool that predicts whether patients with COPD will have a rapid decline in lung function. Such tools can be highly useful in planning treatment strategies and it is important to investigate whether they are accurate. The study will then identify those patients who are likely to have a rapid decline, separate them by the treatment they were receiving, and compare their lung function decline over time. Differences between individual's observed and predicted FEV1 values (calculated from the validated prediction model or a newly developed model) will be described after initiation of maintenance therapies. A matched comparison of FEV1 decline of patients initiated on triple therapy and patients on minimal inhalation therapy will be performed using a multilevel model for change. Conditional negative binomial regression and stratified Cox-regression will be used to analyse differences in exacerbation rates and time to first COPD-related hospitalisation respectively. The study will obtain much needed evidence of whether decline can be reduced by particular treatment regimens and could lead to improved management of this condition.

Study status

Ongoing

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility

ENCePP partner

Contact details

Study institution contact

David Price marjan@opri.sg

Study contact

marjan@opri.sg

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/02/2017

Actual: 13/04/2017

Study start date
Planned: 01/05/2017

Actual: 18/05/2017

Data analysis start date
Planned: 01/06/2017

Date of interim report, if expected
Planned: 01/08/2017

Date of final study report
Planned: 15/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pearl /AstraZeneca

Study protocol

170714_Protocol DIAPLO study_R05016_V1.4.pdf(3.04 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To study the effectiveness of triple therapy on slowing down the rate of FEV1 decline in patients who were identified as being at high risk of rapid FEV1 decline by comparing the rate of FEV1 decline in patients during triple therapy with that of similar patients during minimal therapy or poor adherence to maintenance therapy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

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)

Estimated number of subjects

12000

Study design details

Outcomes

Lung function decline over time (Forced expiratory volume in one second), Occurrence of COPD exacerbations

---

Data analysis plan

Patients diagnosed with mild to moderate COPD, a history of smoking and repeated FEV1 measurements will be included. Initially, the study will validate

an existing prediction model for FEV1 decline under minimal therapy, comparing observed and predicted FEV1 values. Differences between individual's observed and predicted FEV1 values will be described after initiation of maintenance therapies. Analyses will be performed for patients with first maintenance therapy being a single inhaler, dual therapy or triple therapy, separately. In addition, patients initiated on triple therapy will be matched to similar patients on minimal therapy, based on potential confounders. A multilevel model for change (mixed linear regression) will be used to compare the rate of FEV1 decline between matched patients. Conditional negative binomial regression and stratified Cox-regression will be used to analyse differences in exacerbation rates and time to first COPD-related hospitalisation respectively.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Optimum Patient Care Research Database

Data sources (types)

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