Assessing the Utility of Peak Inspiratory Flow as a Predictor for COPD Exacerbations (PIF in COPD)

First published: 14/04/2020
Last updated: 04/06/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/47924

EU PAS number
EUPAS34689

Study ID
47924

DARWIN EU® study
No

Study countries
Denmark
Italy
Korea, Republic of
Malta
Poland
Singapore
Slovenia
Spain

Study description
This is an international, mulitcentre, observational, prospective study into Peak Inspiratory Flow in COPD patients that aims to: A) Determine the prevalence of suboptimal Peak Inspiratory Flow (PIF) and inadequate inhaler choice and assess the baseline

characteristics of these groups. B) Assess the clinical role of PIF and inhaler choice in predicting COPD exacerbations and symptom burden. C) Assess the variability and correlation of PIF with other lung function measurements and CAT score in stable COPD. It is a 12 month study comprising one baseline assessment and 2 follow-up visits at 6 and 12 months.

Study status
Ongoing

Research institution and networks

Institutions

Respiratory Effectiveness Group
First published: 01/02/2024
Last updated 01/02/2024
Institution

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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Primary lead investigator
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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
10/03/2020
Actual:
10/03/2020

Study start date
Planned:
30/09/2020
Actual:
05/11/2020

Date of final study report
Planned:
30/04/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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:
Disease epidemiology

Main study objective:
A) Determine the prevalence of suboptimal Peak Inspiratory Flow (PIF) and inadequate inhaler choice and assess the baseline characteristics of these groups. B) Assess the clinical role of PIF and inhaler choice in predicting COPD exacerbations and symptom burden. C) Assess the variability and correlation of PIF with other lung function measurements and CAT score in stable COPD.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Observational, non-interventional study

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
400

Study design details

Outcomes
1) Prevalence of suboptimal PIF and inadequate inhaler choice. 2) Annual exacerbation rate, exacerbation risk and time to first exacerbation and all-cause hospitalization and mortality associated with different levels of PIF. 3) Association between PIF and symptom burden i.e. CAT score. 4) Annual mortality rate associated with different PIF levels. 5) Variability of PIF over time and the correlation between PIF and other lung function measures (including FEV1, FVC, Inspiratory capacity), CAT scores, T2 markers (nasal polyps and dermatitis) and where available blood biomarkers.

Data analysis plan
Comparison of demographic and clinicals characteristics between those with optimal and suboptimal PIF, and those with adequate vs inadequate inhalers. We will analyse: • Time to first/ risk of exacerbation using Cox regression. • Rates of exacerbation using multivariate negative binomial regression. • The variability of PIF measurements will be assessed with repeated measures and coefficient of variation • The correlation of PIF with other lung function measurements, CAT scores and blood biomarkers will be assessed using Spearman’s rank correlation coefficient. The analyses will control for the effects of age, sex, previous exacerbation history, ICS use, lung function, smoking status, time since last smoking and seasonality (month of the year).

Data management

Data sources

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