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

First published: 14/04/2020

Last updated: 08/08/2024

Study Finalised

Administrative details

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

Finalised

Research institutions and networks

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

Omar Usmani

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: 30/09/2024

Actual: 05/06/2024

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

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.

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