PredictIng the risk for first COPD severe exacerbation (PRECISE-X)

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Last updated: 08/08/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/108395

EU PAS number

EUPAS50803

Study ID

108395

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study aims to examine whether existing COPD risk prediction models are capable of predicting the first severe exacerbations, and if not, develop a risk model for predicting first-time occurrence of severe COPD exacerbation. The model will use common recorded variables as predicting indicators with the main intent to help clinicians to define the individual risk of a severe exacerbation at the time of diagnosis, similar to the cardiovascular risk scores (SCORE, Framlingham).

Study status

Ongoing

Research institutions and networks

Networks

Respiratory Effectiveness Group (REG)

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

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Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/01/2023

Actual: 19/01/2023

Study start date

Planned: 28/02/2023

Actual: 22/04/2024

Data analysis start date

Planned: 01/05/2024

Date of interim report, if expected
Planned: 31/08/2024

Date of final study report
Planned: 30/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca UK Limited

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:

Not applicable

Main study objective:

Observational retrospective database study investigating risk factors for the first severe COPD exacerbation since COPD diagnosis (endpoint 5years), using commonly recorded variables.

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

0

Study design details

Outcomes

1. Identification of the risk factors leading to the first severe COPD-related exacerbation within 5 years of COPD diagnosis. 2. Risk of experiencing ≥1 COPD-related exacerbations. 1. Annualised rate of severe COPD exacerbations. 2. Time of occurrence of severe COPD exacerbations.

Data analysis plan

The study will use an accelerated failure time (AFT) model for prediction. AFT models are flexible survival models that enable the full specification of survival time (unlike the Cox proportional hazard model that leaves baseline hazard unspecified), this enabling prediction of time to the event of interest as well as the cumulative hazard of the event, which can be turned into an estimate of 5-year risk through the relation P(event)=1-exp(-H(t)) where H(t) is the cumulative hazard at time t. For model validation, the study will assess model calibration by drawing the calibration plots and evaluating calibration slope (A) and intercept (B). The model discrimination will be calculated via Receiver Operating Characteristic (ROC) curve analysis and evaluating the Area Under the Curve (AUC), equal to the c-statistic. Finally, the potential clinical utility of the model via Decision Curve Analysis (DCA) will be also analysed and calculated accordingly.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

Other

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