Cardiopulmonary risk model for patients with chronic obstructive pulmonary disease

First published: 07/06/2023
Last updated: 23/04/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/105273

EU PAS number
EUPAS105272

Study ID
105273

DARWIN EU® study
No

Study countries
United Kingdom

Study description
An observational, historical cohort study to construct a risk model that predicts major cardiopulmonary events amongst patients with chronic obstructive pulmonary disease using the OPCRD database

Study status
Ongoing

Research institution and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom
First published: 06/10/2015
Last updated
23/11/2016

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

Contact details

Study institution contact
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Primary lead investigator
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Study timelines

Date when funding contract was signed
Planned:
05/10/2022
Actual:
05/10/2022

Study start date
Planned:
21/10/2022
Actual:
21/10/2022

Date of final study report
Planned:
31/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

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:
Assessment of risk minimisation measure implementation or effectiveness
Disease epidemiology

Main study objective:
To construct a risk model that predicts major cardiopulmonary events (MACRE) in patients with chronic obstructive pulmonary disease (COPD)

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medical condition to be studied
Chronic obstructive pulmonary disease
Myocardial infarction
Cardiac failure

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
131581

Study design details

Outcomes
The outcome will be MACRE, which is a composite of any of the following: • First heart failure hospitalization after the index date, • First diagnosis or hospitalization for myocardial infarction, or occurrence of coronary revascularization after the index date, • First severe COPD exacerbation, defined by COPD-related hospitalizations, after the index date, and • Non-cancer-related mortality.

Data analysis plan
A predictive model will be constructed for the outcome (MACRE) using Fine-Gray competing risk regression, with cancer-related mortality as the only competing event. The hold-out method will be used, with a randomly selected 80% of the cohort being the development dataset and the remainder 20% being the validation dataset. Elastic net will be used for variable selection and regularization. Discrimination of the resultant model will be evaluated within the derivation cohort using Harrell’s C-index. Calibration will be assessed quantitatively using the Greenwood-Nam-D'Agostino test and/or the Brier score, as well qualitatively as using an overlaid plot of the predicted and observed (Kaplan-Meier) freedom from the composite outcome for each quintile as grouped by the predicted risk. Prognostic value of the predicted risks generated by the resultant model will be additionally evaluated by means of survival analysis.

Data management

Data sources

Data source(s)
Optimum Patient Care Research Database

Data sources (types)
Electronic healthcare records (EHR)

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