Cardiopulmonary risk model for patients with chronic obstructive pulmonary disease

First published: 07/06/2023

Last updated: 23/04/2024

Study Ongoing

Administrative details

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 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

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

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

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 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