CARDIO-PULSE: CARDIOvascular disease and Chronic Obstructive PULmonary DiseaSE: a real-world observational study in Australian primary care

First published: 05/03/2026

Last updated: 05/03/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000940

Study ID

1000000940

DARWIN EU® study

No

Study countries

Australia

Study description

The study will be an observational cohort study using data from Australian primary care electronic medical records from the Optimum Patient Care Research Database Australia (OPCRDA) The OPCRDA is a real-world, longitudinal, research database that is maintained by Optimum Patient Care Australia (OPCA). It contains anonymised health data from over one million patients from primary care across Australia.

The population will comprise adults aged ≥40 years with COPD, defined as a documented diagnosis of COPD and a prescription for COPD medication in the previous 2 years, who are clinically active (prescription and/or consultation data) on the OPCRDA database from 1 January 2021.The study will have 2 study aims.

For the first study aim, people with COPD will be matched by age/gender/smoking status to a cohort of individuals without COPD. Individuals will be followed up from 1 January 2021 for 3–5 years and incidence of new-onset cardiovascular disease (CVD) events, CVD risk score assessments and absolute risk scores will be compared and the predictors of future CVD events in high-risk COPD will be explored.

For the second study aim, the cohort will be restricted to individuals who are at high risk (i.e. have ≥2 exacerbations in the previous 24 months) and have at least one exacerbation within the follow-up period. The first exacerbation will be taken as the index date. People with pre-existing CVD (defined as stroke, myocardial infarction, angina, peripheral arterial disease, atrial fibrillation, and/or heart failure) will be compared to those without CVD in relation to time to COPD maintenance therapy change and incidence of new-onset CVD.

Study status

Planned

Research institutions and networks

Institutions

Optimum Patient Care Australia

Australia

First published: 01/02/2024

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Institution | Not-for-profit

Observational and Pragmatic Research Institute (OPRI)

Networks

Optimum Patient Care (OPC) Network

United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 16/06/2025

Network | ENCePP partner

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Planned: 28/10/2026

Study start date
Planned: 01/11/2026

Date of final study report
Planned: 31/07/2026

Sources of funding

- Other

More details on funding

Funding for this study was partially provided by OPCA and AstraZeneca

Study protocol

CARDIO PULSE_Protocol_V4.1.pdf (798.31 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Study design:

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Main study objective:

The overarching aim of this study is to identify priority areas of action in relation to people with comorbid COPD-CVD and people with COPD at risk of developing CVD. This includes exploring the risk of CVD among high-risk COPD patients and how CVD risk assessments can be used to optimise prevention and treatment strategies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

The population will comprise adults aged ≥40 years with COPD, defined as a documented diagnosis of COPD and a prescription for COPD medication in the previous 2 years, who are clinically active (prescription and/or consultation data) on the OPCRDA database from 1 January 2021

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

5500

Study design details

Setting

Study data will be extracted through the OPCRDA, which contains anonymised, research quality data from Australian general practice centers. The population will comprise adults aged ≥40 years with COPD, defined as a documented diagnosis of COPD and a prescription for COPD medication in the previous 2 years, who are clinically active (prescription and/or consultation data) on the OPCRDA database from 1 January 2021.The study will have 2 study aims.

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Outcomes

Primary outcomes will be new onset CVD events, CVD risk assessment and COPD medication therapy change

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Data analysis plan

We will use Poisson regression (or negative binomial if overdispersion is present) to calculate IRR (95% CI) of new-onset CVD events by COPD status (Objective 1a), also describing the influence of clinical characteristics, previous exacerbations and drug therapy class (Objective 1e).

We will describe CV risk assessments used and calculate the prevalence rate ratio (Poisson/negative binomial regression) of CVD risk score assessments and absolute risk scores by COPD status (Objectives 1b,1c). The influence of clinical characteristics, previous exacerbations and drug therapy class will also be

investigated (Objective 1d).

Time from COPD exacerbations to COPD maintenance therapy change (Objectives 2a,2b) by comorbid CVD status will be assessed using time-to-event analyses (Cox regression and Kaplan-Meier plots), also stratified by therapy class at baseline and class regimen. No therapy changes will be treated as censored data at 12 months post-index date. The findings will be presented using graphs and hazard ratios (HR), with 95% confidence intervals (CI).

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), other

Optimum Patient Care Research Database Australia (OPCRDA)

Data sources (types)

Disease registry

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