An Australian based Study on the Patterns of Short Acting Beta-2 Agonist (SABA) use and Its Potential Effects on Asthma Control (SABINA Australia)

First published: 03/07/2023

Last updated: 21/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS105682

Study ID

105683

DARWIN EU® study

No

Study countries

Australia

Study description

An observational, cross-sectional study describing SABA prescribing, use and potential effects among asthma patients in Australia, using a unique platform of linked electronic healthcare records and patient questionnaires (OPCRDA).

Study status

Ongoing

Research institutions and networks

Institutions

Optimum Patient Care Australia

Australia

First published: 01/02/2024

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Institution | Not-for-profit

Contact details

Study institution contact

David Price dprice@opri.sg

Study contact

dprice@opri.sg

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 25/11/2021

Actual: 25/11/2021

Study start date
Planned: 01/12/2021

Actual: 01/12/2021

Data analysis start date
Planned: 05/01/2022

Actual: 05/01/2022

Date of final study report
Planned: 01/12/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca Australia, Optimum Patient Care Australia

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

Drug utilisation

Main study objective:

To determine the pattern and trend of SABA prescriptions in Australian asthma patients, selected in a cross-sectional manner as per the International SABINA program.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Asthma

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

21.000

Study design details

Outcomes

Describe the demographic and clinical features of the asthma population Estimate SABA prescription per patient (by canisters per year) and describe the patients within the different SABA groups Estimate ICS and combination ICS/LABA prescription per patient and describe the patients within the different ICS groups, Describe the relation between SABA usage and number of severe exacerbations in the past 12 months per patient Describe the relation between

SABA usage and asthma control (as defined by GINA). Describe the relation between SABA usage and number of OCS bursts in the past 12 months per patient.

Data analysis plan

Demographic and clinical features of the asthma patients will be descriptively summarised. Additionally, descriptive analysis will be conducted by asthma severity, at each GINA step, for the overall population and for the regions. Summary statistics will be presented for primary variables overall. Further contingency tables will be generated for the three primary variables and prespecified categories of SABA prescription. Use SABA and ICS prescription per patient and describe patients within the different pre-specified categories of SABA authorisation. Summary statistics will be produced The association between the prespecified categories of SABA authorisation for patients with different disease severity defined by the GINA steps and health outcomes will be estimated. For each type of the health outcomes, model-based regression analyses for the overall population will be carried out and the confounders will be selected through stepwise forward selection.

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 Australia (OPCRDA)

Data sources (types)

Electronic healthcare records (EHR)

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