Risk of switching to angiotensin-II receptor blocker therapy in people with asthma who initiate ACE inhibitor therapy compared to the general population: a retrospective cohort study

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Administrative details

EU PAS number
EUPAS35083
Study ID
35084
DARWIN EU® study
No
Study countries United Kingdom

Study description

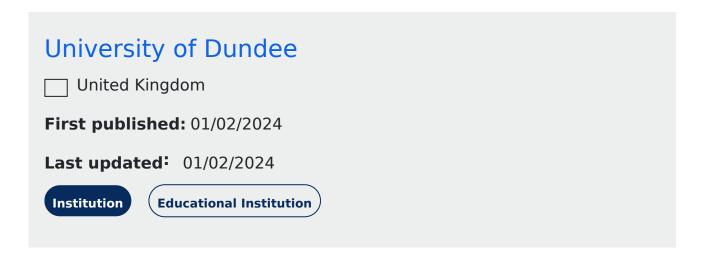
UK population-based retrospective observational cohort study

Study status

Ongoing

Research institutions and networks

Institutions



Contact details

Study institution contact

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Study contact

d.r.z.morales@dundee.ac.uk

Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/05/2016 Actual: 18/10/2016

Study start date

Planned: 23/08/2016 Actual: 11/04/2017

Data analysis start date

Planned: 13/02/2018 Actual: 11/12/2018

Date of final study report

Planned: 16/06/2020

Sources of funding

• Non-for-profit organisation (e.g. charity)

More details on funding

Tenovus Scotland

Study protocol

EUPAS35083-35082.pdf (187.19 KB)

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

Main study objective:

To examine whether people with asthma are at a greater risk of ACE inhibitor intolerance by examining whether they are more likely to switch to an angiotensin-II receptor blocker (ARB) after initiation of ACE inhibitor therapy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C09AA) ACE inhibitors, plain

ACE inhibitors, plain

(C09CA) Angiotensin II receptor blockers (ARBs), plain

Angiotensin II receptor blockers (ARBs), plain

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

500000

Study design details

Outcomes

Switching to an ARB within 6 months of ACE inhibitor discontinuation

Data analysis plan

Hazard ratios will be calculated using Cox proportional hazards regression for the risk of switching to an ARB after initiation of ACE inhibitor therapy in people with asthma compared to the general population. People with COPD will act as a negative control.

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)

Clinical Practice Research Datalink

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Unknown			
Check completer	ness		
Unknown			

Check stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No