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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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/35084

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 institution and networks

Institutions

University of Dundee

United Kingdom
First published: 01/02/2024
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01/02/2024
Institution
Educational Institution

Contact details

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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
100000095102
ACE inhibitors, plain
100000095140
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

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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

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

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No