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

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

University of Dundee

United Kingdom

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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

(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

500.000

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