Risk of angiotensin converting enzyme inhibitor intolerance in asthma compared to the general population

First published: 13/02/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS33586

Study ID

33587

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study will examine the risk of intolerance to angiotensin converting enzyme (ACE) inhibitors in asthma compared to the general population. Intolerance will be defined by switching to an angiotensin-II receptor blocker after initiation of ACE inhibitor therapy.

Study status

Ongoing

Research institutions and networks

Institutions

University of Dundee

United Kingdom

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Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 11/07/2016

Actual: 11/07/2016

Study start date
Planned: 18/07/2016

Actual: 18/07/2016

Data analysis start date
Planned: 10/04/2017

Actual: 10/04/2017

Date of final study report
Planned: 24/02/2020

Sources of funding

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

More details on funding

Tenovus Scotland, Internal University of Dundee resources

Study protocol

EUPAS33586-33585.pdf (179.86 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

Drug utilisation

Main study objective:

The aim of this study is to examine ACE inhibitors drug utilisation in people with asthma. It will then evaluate the risk of switching to angiotensin-II receptor blockers in people with asthma with ACE inhibitor therapy compared to the

general population whilst also examining the characteristics of switchers in people with asthma.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C09A) 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

640.000

Study design details

Outcomes

The outcomes include switching to an angiotensin-II receptor blocker after initiation of ACE inhibitor therapy in people. There will be a descriptive component examining the characteristics of switchers. ACE inhibitor and angiotensin-II receptor blocker drug utilisation in asthma.

Data analysis plan

An open cohort of adults with active asthma will be created. All patients starting ACE inhibitor therapy will be identified from the asthma and general population. People switching to an angiotensin-II receptor blocker (ARB) will be identified. The characteristics of interest on the risk of switching include: asthma and its severity, age, gender, body mass index, smoking status and socioeconomic deprivation. Patients with COPD will also be evaluated as a comparison. The cohort study will be analysed using COX regression adjusting for the aforementioned characteristics/confounders with routine checks of the proportional hazards assumption.

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 source(s), other

CPRD

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