Trends in co-prescribing of renin-angiotensin system (RAS)-acting agents in France, Germany and the UK during 2001 - 2012

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Study Finalised

Administrative details

EU PAS number

EUPAS4389

Study ID

33362

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ United Kingdom

Study description

The present study aims to describe the extent and the patterns of co-prescription of RAS-acting agents in three large EU countries in the period 2001-2012 including in patients with diabetes mellitus (DM) and chronic kidney disease (CKD). This will be done using the European Medicines Agency's in-house IMS Health databases. Co-prescription will be defined as the prescription of different drug classes made on the same day and by the same physician. By reason of the large populations in the three study countries, which approximate to 40% of the total EU population, these population-based data may contribute to the assessment of the public health impact of any safety concern in relation to the co-prescription of RAS-acting agents in the EU.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/07/2013

Actual: 22/07/2013

Study start date

Planned: 31/07/2013

Actual: 31/07/2013

Date of final study report

Planned: 02/09/2013

Actual: 27/08/2013

Sources of funding

- EMA

Study protocol

RAS Draft Protocol - website.pdf(128.83 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To provide drug utilisation data on dual blockade of the renin-angiotensin system (RAS) by describing the extent and the pattern of co-prescription of different RAS-acting agents prescribed on the same day and by the same physician in France, Germany and the UK

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C09) AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

Medical condition to be studied

Hypertension

Diabetes mellitus

Population studied

Short description of the study population

All patients with at least one consultation in the calendar year in question receiving a prescription of RAS-acting agents as recorded in the IMS Health databases in France, Germany and the UK.

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)

Special population of interest

Renal impaired

Estimated number of subjects

18000000

Study design details

Outcomes

Estimation of prevalence of co-prescription of RAS-acting agents in France, Germany and the UK,Description of pattern of co-prescription of RAS-acting agents in France, Germany and the UK over time (2001-2012), Estimation of prevalence and pattern of RAS-acting agent co-prescription in patients with Diabetes Mellitus or with Chronic Kidney Disease.

Data analysis plan

This analysis is descriptive in nature. In each country the following will be investigated:• Prevalence: number and percentage of patients prescribed any

drug acting on RAS and with any co-prescription of these drugs in 2012:o In the general population included in the database,o In each of the following populations: patients treated with antihypertensive drugs, patients with diabetes and patients with chronic kidney disease.• Prescription pattern: percentage of patients prescribed with any drug acting on RAS and with any co-prescription of these drugs between 2001 and 2012:o In the general population included in the database,o In each of the two populations: patients with diabetes and patients with chronic kidney disease.Co-prescription will be defined as the prescription of different drug classes made on the same day and by the same physician.

Documents

Study results

EMA_RAS_Study Report.pdf(989.46 KB)

Data management

Data sources

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