Validation of a US Health Care Claims Database for the Study of Cardiovascular and Neoplasm Events among Users of Treatments for Overactive Bladder

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Study Finalised

Administrative details

EU PAS number

EUPAS8517

Study ID

30783

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

Comprehensive Health Insights

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Institution

Contact details

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Primary lead investigator

Brandon Suehs

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/07/2014

Study start date

Actual: 01/10/2014

Date of final study report
Planned: 31/07/2015

Actual: 15/07/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Global Development

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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

Other

If ‘other’, further details on the scope of the study

Validation of the Humana database for the study of cardiovascular and neoplasm events in users of treatments for overactive bladder

Data collection methods:

Secondary use of data

Main study objective:

To characterize users of antimuscarinic OAB medications. To estimate incidence rates of cardiovascular and neoplasm outcomes among initiators of antimuscarinic OAB medications.To validate claims-based identification algorithms for cardiovascular and neoplasm events.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G04BD04) oxybutynin

oxybutynin

(G04BD07) tolterodine

tolterodine

(G04BD08) solifenacin

solifenacin

(G04BD09) trospium

trospium

(G04BD10) darifenacin

darifenacin

(G04BD11) fesoterodine

fesoterodine

Medical condition to be studied

Hypertonic bladder

Population studied

Short description of the study population

Users of antimuscarinic medications for the treatment of Overactive Bladder (OAB). Patients newly initiated on antimuscarinic OAB medication between 2007 and 2013 were identified based on pharmacy claims data, and date of initiation of OAB medication was the index date for cohort entry.

Patients must follow the following criteria:

1. Medicare Advantage Prescription Drug (MAPD) or commercial health plan members with first dispensing for an antimuscarinic OAB drug (oxybutynin,

tolterodine, darifenacin, solifenacin, trospium, fesoterodine) between 01 January 2007 through 31 December 2013.
2. Member had both pharmacy and medical benefit coverage during their health plan enrollment period.
3. Age 18 years or older at the time of first prescription of a drug of interest.
4. Member had at least 6 months of continuous enrollment (defined as gap = 0 days) in the health plan prior to the index date. Member should have no prior dispensings of that same medication in the previous 6 months.

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

Other

Special population of interest, other

Overactive Bladder patients

Estimated number of subjects

160000

Study design details

Outcomes

CV endpoints: AMI, stroke, CV mortality, all-cause mortality, major adverse cardiac events (MACE)Composite cancer endpoints: lung & bronchus, colon & rectum, melanoma of skin, urinary bladder, non-Hodgkin lymphoma, kidney & renal pelvis, pancreas, prostate (males), breast (females), corpus uteri (females)

Data analysis plan

Descriptive summaries of patient demographic, plan enrollment, baseline clinical characteristics, health service utilization, and healthcare costs measures will be produced. Incidence of cardiovascular and neoplasm outcomes will be assessed. Positive and negative predictive values for claims-based identification algorithms will be deteremined.

Documents

Study results

178-cl-130-clrr-02-disc01-en-final-02.pdf (2.39 MB)

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 sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Medical record abstraction

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