A Study of Treatments for Overactive Bladder: Incidence and Validation of Cardiovascular and Cancer Outcomes and Examination of Drug-Use Patterns in a US Health Care Claims Data Environment (OAB)

First published: 04/12/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7924

Study ID

29827

DARWIN EU® study

No

Study countries

United States

Study description

This is a retrospective cohort study estimating the incidence rates of cardiovascular and cancer outcomes among initiators of currently available antimuscarinic drugs (oxybutynin, tolterodine, darifenacin, solifenacin, trospium, or fesoterodine) from 01 January 2004 through 30 September 2012. The study calculated incidence rates of the following endpoints : - CV: including acute myocardial infarction, stroke, all-cause mortality, CV mortality and a composite MACE endpoint.- Neoplasm endpoint: including the 10 most commonly occurring in the general population.Medical record abstraction for validation of a random sample of claims-identified cases is included.

Study status

Finalised

Research institutions and networks

Institutions

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

Contact details

Study institution contact

Kathleen Mortimer veena.hoffman@optum.com

Study contact

veena.hoffman@optum.com

Primary lead investigator

Kathleen Mortimer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/09/2012

Actual: 17/09/2012

Study start date

Planned: 12/11/2012

Actual: 12/11/2012

Data analysis start date

Planned: 04/01/2013

Actual: 04/01/2013

Date of interim report, if expected

Planned: 17/06/2013

Actual: 17/06/2013

Date of final study report

Planned: 01/12/2014

Actual: 17/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Global Development, Inc.

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

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

Validation of algorithms used in the ORD database for the study of CV and neoplasm events in users of treatments for overactive bladder

Data collection methods:

Secondary use of data

Main study objective:

Characterize users of antimuscarinic OAB drugsDescribe patterns of usage of OAB drugsValidate algorithms used for the diagnosis of study endpoints.Estimate IRs of study endpoints in new users of antimuscarinic OAB drugsConfirm CV outcomes and selected cancer outcomes via medical record review Refine the study size and statistical power assessment for post-marketing safety studies

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Database Validation Study

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

Urinary incontinence

Population studied

Short description of the study population

Initiators of currently available antimuscarinic drugs (oxybutynin, tolterodine, darifenacin, solifenacin, trospium, or fesoterodine) from 01 January 2004 through 30 September 2012.

Subjects in the study were required to meet the following criteria:
1. Have a first dispensing for an antimuscarinic drug (oxybutynin, tolterodine, darifenacin, solifenacin, trospium, or fesoterodine) during the study period of 01 January 2004 through 30 September 2012
2. Have reached age 18 years and older at the time of first dispensing of the antimuscarinic drug during the study period
3. Have at least 6 months of continuous enrollment in the health plan (thereby providing medical and drug dispensing history data) before the first dispensing of the antimuscarinic drug

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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

205.422

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

All analyses will be descriptive in nature both for the health insurance claims data and the medical record review data. Characterization of over active bladder (OAB) drug users included the summarization of the relevant baseline covariates such as demographics, plan membership characteristics, diagnosis of OAB or incontinence and other comorbidities, along with prescription drug history, and health care services.Patterns of medication use for each antimuscarinic drug were examined, including characteristics of patients who use a drug immediately after drug launch, switching between antimuscarinic drugs, use of combination therapies, and consistency of use over the study period. Incidence rates of claims-identified CV Outcomes and cancer outcomes were determined. A random sample of claims-identified CV and cancer cases was validated by review of the medical record. Similarly, a sample of claims-identified cancer-related covariates was validated.

Documents

Study results

178-cl-115-clrr-02-disc01-en-final-02_redacted.pdf (1.87 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 source(s), other

Optum Research Database (ORD)

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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

Unknown