5ARI and Prostate Cancer Mortality Study (116059)

First published: 13/06/2013
Last updated: 24/05/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/48165

EU PAS number
EUPAS4129

Study ID
48165

DARWIN EU® study
No

Study countries
United States

Study description
This retrospective cohort study will assess the association of benign prostatic hyperplasia (BPH) treatment (5-alpha reductase inhibitors (5ARI) and alpha-blocker medications) with the occurrence of prostate cancer related mortality. This study will also assess a number of secondary endpoints including prostate cancer mortality or metastatic prostate cancer, and all cause mortality.

Study status
Finalised

Research institution and networks

Institutions

Kaiser Permanente Southern California (KPSC)

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Institution

Contact details

Study institution contact
GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Study contact

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Primary lead investigator
GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
15/11/2012

Study start date
Actual:
15/11/2012

Date of interim report, if expected
Planned:
28/02/2015

Date of final study report
Planned:
31/03/2016
Actual:
31/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline, LLC

Study protocol

Redacted Final Avodart Mortality Protocol 11 15 12_116059 pdf draft 001_Redacted.pdf (993.66 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 topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:
Secondary data collection

Main study objective:
To assess the risk of prostate cancer mortality associated with use of 5ARIs, with or without alpha-blockers, compared to alpha-blockers in men treated with BPH medications.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine, other
dutasteride and finasteride

Population studied

Short description of the study population
All men age 50 years and older treated with a BPH medication (5ARI and/or alphablocker) will be eligible for inclusion. Men using alpha-blocker medications were selected as the comparison group for this study as alpha-blockers are the most common treatment for BPH and men with BPH or lower urinary tract symptoms that are untreated for their condition are likely to be very different from those with severe enough symptoms to seek medical care and take medication.

INCLUSION CRITERIA:
1. Male
2. A new prescription for BPH medication (5ARI and/or alpha-blocker) in 1992 or later that is identified as appropriate treatment for BPH/LUTS from the National Pharmacy guidelines
3. Treatment with BPH medication initiated prior to Jan1, 2008.
4. Age 50 years or older at time of treatment with 5ARI or alpha-blocker
5. At least 1-year of coverage in the healthcare system before the first prescription for BPH medication (5ARI and/or alpha-blocker).
6. At least 3 consecutive prescriptions (90 days of supply) for a BPH medication (5ARI and/or alpha-blocker)

EXCLUSION CRITERIA:
1. Diagnosis of prostate cancer any time before the first prescription for BPH medication (5ARI and/or alpha-blocker).
Diagnosis of prostate cancer within 3 months after first BPH medication (5ARI and/or alpha-blocker)
Patients treated with finasteride 1mg prior to BPH medication. Finasteride 1mg is the dose approved for androgenic alopecia and as the target population for this

study is men with treated BPH, we will exclude all men treated with the 1mg dose. Patients treated with 1mg Finasteride will be characterized in terms of which study exposure group they would have transitioned into (5ARI or alphablocker) had they been included in the study population, and basic baseline demographic factors.

Age groups
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
Prostate cancer patients

Estimated number of subjects
219000

Study design details

Outcomes
To acess prostate cancer mortality. To access combined endpoint of prostate cancer mortality or metastatic cancer, and all cause mortality.

Data analysis plan
Cox proportional hazard regression models will be fit in the overall data set to compare prostate cancer mortality between groups while adjusting for the pre-treatment characteristics.

Documents

Study results
gsk-116059-clinical-study-report-redact.pdf(4.09 MB)

Data management

Data sources

Data source(s)
Drug claims information system

Data source(s), other
PHARM

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