5ARI and Prostate Cancer Mortality Study (116059)

First published: 13/06/2013

Last updated: 24/05/2024

Study Finalised

Administrative details

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 institutions and networks

Institutions

Kaiser Permanente Southern California (KPSC)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

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 use of data

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

Medicinal product name, 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

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)

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