Cardiovascular outcomes among patients with castration-resistant prostate cancer: A comparative safety study within US real world databases

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Study Planned

Administrative details

EU PAS number

EUPAS35544

Study ID

35545

DARWIN EU® study

No

Study countries

☐ United States

Study description

The proposed study will include clinical characterization and population-level effect estimation (observational causal inference) of men with castrate resistant prostate cancer using administrative claims databases which include nation-wide samples of patients insured in the United States (US). We plan to conduct a new user comparative cohort design to compare incidence of myocardial infarction and stroke among men with castrate resistant prostate cancer who are initiating treatment with either abiraterone acetate plus prednisone or enzalutamide. The study period will begin after August 31, 2012 since before that date enzalutamide was not FDA-approved for the treatment of CRPC in the US. Following completion of a feasibility analysis in which we will assess diagnostics to see whether comparisons between abiraterone and enzalutamide are possible, we will compare incidence of various outcomes including ischemic stroke, hemorrhagic stroke, heart failure, and acute myocardial infarction. Patients within each treatment cohort will be described including demographics, conditions, drugs, and procedures used in the time preceding the index date. For calculation of incidence rates, the number of persons with each event, the incidence proportion, and the incidence rate adjusted for person-time according to each at-risk time window for each study population and each of the outcomes of interest will be reported. For the purpose of contextualizing the event rates and quantifying relative risk while controlling for additional confounding factors, a new user cohort design will be used to conduct comparative analyses if the exposed (abiraterone) population can be appropriately matched to the selected comparator population (enzalutamide) based on a defined set of patient and clinical characteristics, using propensity score matching. Cox proportional hazards will be used to estimate the hazards of each outcome in the target cohort, relative to the comparator cohort.

Study status

Planned

Research institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dina Gifkins

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/05/2020

Study start date

Planned: 29/05/2020

Date of final study report
Planned: 31/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

Among patients with castration-resistant prostate cancer (CRPC), compare new users of abiraterone acetate plus predniso(lo)ne to new users of enzalutamide with respect to hospitalization for the cardiovascular morbidity outcomes of ischemic stroke, hemorrhagic stroke, heart failure, and acute myocardial infarction

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

ABIRATERONE ACETATE

ENZALUTAMIDE

Medical condition to be studied

Cardiovascular disorder

Population studied

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

3000

Study design details

Outcomes

Incidence of cardiovascular morbidity including ischemic stroke, hemorrhagic stroke, heart failure, and myocardial infarction

Data analysis plan

Characteristics of patients within each treatment cohort will be described during the time preceding the index date. For calculation of incidence rates, the number of persons with each event, the incidence proportion, and the incidence rate adjusted for person-time according to each at-risk time window for each study population and each of the outcomes of interest will be reported. A new user cohort design will be used to conduct comparative analyses if the exposed (abiraterone) population can be appropriately matched to the selected comparator population (enzalutamide) based on a defined set of patient and clinical characteristics, using propensity score matching. Cox proportional hazards will be used to estimate the hazards of each outcome in the target cohort, relative to the comparator cohort. The number of persons, amount of time-at-risk, and number of outcomes in each cohort will also be reported. Additionally, Kaplan-Meier plot swill be generated.

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

Longitudinal Prescription Data - US

Data sources (types)

Administrative healthcare records (e.g., claims)

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