An Observational Study to Compare cardiovascular related hospitalization in chemo-naïve Patients with Metastatic Castration Resistant Prostate Cancer, treated with Enzalutamide or Abiraterone in daily practice in Germany (AVENGER)

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Study Finalised

Administrative details

EU PAS number

EUPAS104771

Study ID

105061

DARWIN EU® study

No

Study countries

Germany

Study description

This observational study will be based on anonymized German claims data provided by two German health insurance funds. The primary objective of the study is to analyze and compare the risk of cardiovascular (CV) events in chemotherapy-naïve patients with metastatic castration resistant prostate cancer (mCRPC) who initiated treatment with enzalutamide or abiraterone. The secondary objectives of this study are to: • Analyze and compare the CV event rate (including recurrent events) in chemotherapy-naïve patients with mCRPC who initiated treatment with enzalutamide or abiraterone • Describe and compare characteristics of chemotherapy-naïve patients with mCRPC initiating treatment with enzalutamide or abiraterone • Describe treatment sequences and durations of treatments following enzalutamide or abiraterone initiation in chemotherapy-naïve patients with mCRPC

Study status

Finalised

Research institutions and networks

Institutions

Ingress-Health HWM

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Institution

A Cytel company

Contact details

Study institution contact

Clinical Trial Registration Department

clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Müller Sabrina

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 23/06/2022

Study start date

Planned: 15/05/2023

Actual: 15/05/2023

Data analysis start date
Planned: 01/12/2023

Actual: 15/05/2024

Date of final study report
Planned: 20/05/2024

Actual: 15/05/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe Ltd.

Study protocol

9785-ma-3497 - original protocol-disclosure-redacted (1).pdf(1.72 MB)

9785-ma-3497-protocol-v2-incorp-nonsubst-amend-01-disclosure-redacted.pdf
(1.62 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

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

To analyze and compare the risk of CV events in chemotherapy-naïve patients with mCRPC who initiated treatment with enzalutamide or abiraterone.

Main study objective:

The primary objective of this study is to analyze and compare the risk of CV events in chemotherapy-naïve patients with mCRPC who initiated treatment with enzalutamide or abiraterone.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective, non-interventional cohort study

Study drug and medical condition

Medical condition to be studied

Hormone-refractory prostate cancer

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

2418

Study design details

Outcomes

Time to first CV event, defined as CV-related hospitalization. • Number of CV events per patient, defined as CV-related hospitalizations • Baseline characteristics: age, Charlson comorbidity index, cardioembolic risk score, presence of specific comorbidities, number of urologist visits, number of hospitalizations • Treatment sequences and durations of treatments

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Data analysis plan

• Matching of the comparative groups via propensity score model. • Primary outcome: Kaplan-Meier analysis and Cox Proportional Hazard model to estimate hazard ratio, 95% confidence interval and p-value • Descriptive analysis for baseline characteristics secondary outcome. • Treatment sequences and durations secondary outcome: Descriptive analysis, Kaplan-Meier analysis.

Data management

Data sources

Data source(s), other

AOK PLUS Germany, GWQ ServicePlus Germany

Data sources (types)

Other

Data sources (types), other

This study is a retrospective non-interventional database analysis utilizing German claims data provided by the cooperating sickness funds.

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