Clinical experience with cabazitaxel in patients with metastatic castrate resistant prostate cancer (ECLIPSE) (ELIPSE)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/19827

EU PAS number

EUPAS19826

Study ID

19827

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A multi-centre, observational, retrospective research study of patients with metastatic castrate resistant prostate cancer (mCRPC) who have received cabazitaxel in England. The primary objective is to describe the anti-cancer treatment pathways for patients who have received cabazitaxel following prior docetaxel treatment

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Study status

Finalised

Research institutions and networks

Institutions

Sanofi

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Institution

Multiple centres: 5 centres are involved in the study

Contact details

Study institution contact

Medical Information Sanofi

Study contact

uk-medicalinformation@sanofi.com

Primary lead investigator

Medical Information Sanofi

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 25/03/2015

Study start date
Actual: 27/03/2015

Date of final study report
Actual: 07/11/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

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

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

Primary objective: To describe the anti-cancer treatment pathways for patients who have received cabazitaxel following prior docetaxel treatmentSecondary objectives:To describe the clinical outcomes of patientsTo describe the characteristics of patientsTo describe side effects associated with cabazitaxel use

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational retrospective study

Study drug and medical condition

Additional medical condition(s)

Metastatic castrate resistant prostate cancer

Population studied

Short description of the study population

Male patients diagnosed with metastatic castrate resistant prostate cancer (mCRPC) and had received cabazitaxel following failure of previous docetaxel treatment.

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)

Special population of interest

Other

Special population of interest, other

Metastatic castrate resistant prostate cancer patients

Estimated number of subjects

150

Study design details

Data analysis plan

Analyses are descriptive in nature.Nominal variables are described with frequencies and percentages, while ordinal variables are presented as medians and interquartile ranges (IQR). Time-to-event variables (progression-free survival PFS and overall survival OS) were analysed by the Kaplan-Meier method with data presented as survival plots and summarised as median, standard error (SE) and 95% confidence intervals 95% CI, within the follow up period available for each patient (i.e. patients still living at the date of data collection werecensored at the date of data collection for analysis of OS and patients still alive and not recorded as progressing at the time of data collection were censored on that date for analysis of PFS).

Documents

Study results

SR Synopsis v1.0 07Nov2016-anonymised scan.pdf(2.75 MB)

Data management

Data sources

Data sources (types)

Disease registry

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