A Drug Utilization Study of Xofigo Use in Sweden

First published: 11/02/2015

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8494

Study ID

29028

DARWIN EU® study

No

Study countries

☐ Sweden

Study status

Finalised

Research institutions and networks

Institutions

NA

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG clinical-trials-contact@bayer.com

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/10/2014

Actual: 10/10/2014

Study start date

Planned: 01/05/2015

Actual: 15/04/2015

Date of final study report

Planned: 15/12/2017

Actual: 19/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

Xofigo_DUS_in_Sweden_Study_Protocol_Final_Oct_10_2014.pdf (366.73 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the extent of potential off-label use of Xofigo in Sweden

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Single-arm descriptive observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(V10XX03) radium (223Ra) dichloride

radium (223Ra) dichloride

Medical condition to be studied

Prostate cancer stage II

Population studied

Short description of the study population

Patients receiving Xofigo with data recorded at nuclear medicine centers in Sweden between 01 July 2014 and 30 June 2016 were included in the study

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

Prostate cancer patients

Estimated number of subjects

200

Study design details

Outcomes

1.To evaluate the extent of potential off-label use of Xofigo in Sweden2.Proportion of being women of Xofigo use3.Proportion of being children of Xofigo use4.Proportion of bone metastasis but having a diagnosis of other cancer than mCRPV5.Dosage of Xofigo (kBq/kg)6.Proportion of participants of dose outside label recommendation

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Data analysis plan

This is a single arm descriptive observational drug utilization study based on secondary data collection. This study is not aimed to confirm or reject pre-defined hypotheses. Statistical analyses will be descriptive in nature. All variables will be analyzed descriptively with appropriate statistical methods.

Documents

Study results

17399_EU-PAS_Abstract.pdf (61.73 KB)

Study report

17399_CSR_EU PAS register.pdf (321.1 KB)

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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Swedish National Cancer Registry

Data sources (types)

Disease registry

Other

Data sources (types), other

Nuclear medicine centers in Sweden

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