Use of degarelix among patients with prostate cancer in daily practice

First published: 08/11/2018

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS23879

Study ID

28608

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A population-based cohort study will be carried out using the UK's general practitioner database, Optimum Patient Care Research Database (OPCRD), which includes prostate cancer patients initiating treatment of degarelix,

leuprorelin, goserelin or triptorelin from 2010 till present. In this study, we will describe the characteristics, cardio events and urinary tract infections among patients with prostate cancer using degarelix, leuprorelin, goserelin or triptorelin in UK's primary care.

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution **Educational Institution** **Laboratory/Research/Testing facility**

ENCePP partner

Contact details

Study institution contact

David Price dprice@opri.sg

Study contact

dprice@opri.sg

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2018

Actual: 01/02/2018

Study start date

Planned: 20/03/2018

Actual: 20/03/2018

Data analysis start date

Planned: 30/04/2018

Actual: 08/05/2018

Date of final study report

Planned: 31/05/2018

Actual: 22/05/2018

Sources of funding

- Other

More details on funding

Harvey Walsh

Study protocol

OPCG-1802_Protocol for Degarelix_V1.1.pdf(267.44 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The aim of the study is to describe the use of degarelix among patients with prostate cancer in UK’s primary care.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Historical cohort database study

Study drug and medical condition

Name of medicine

FIRMAGON

Population studied

Short description of the study population

Patients with prostate cancer who are new users of degarelix, leuprorelin, goserelin or triptorelin and are registered at a general practice from 2010 till present.

Inclusion criteria:

• Evidence of prostate cancer: an ever diagnostic code (Quality Outcomes Framework (QOF) defined) for prostate cancer or a diagnostic code for surgery, chemotherapy or radiotherapy plus a prescription of degarelix, leuprorelin, goserelin or triptorelin before or at IPD;

• Patients who have at least one record of degarelix, leuprorelin, goserelin or triptorelin;

• Each patient has to be registered with a general practitioner (GP) for at least one year before the IPD;

• Patients have to be actively registered from 2010 till present, i.e. until latest available data

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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

8825

Study design details

Outcomes

the number of ‘switchers’ to second line treatment (leuprorelin, goserelin, triptorelin or degarelix), cardio events and urinary tract infections from the year 2010 till present.

Data analysis plan

An exploratory analysis of variables at baseline or during follow-up (switching to second line treatment, cardio events, or urinary tract infections) will be carried out:Results are reported as: ● Continuous variables:o Sample size (n) (standard deviation (SD)) and percentage non-missingo Median and Interquartile Range (25th and 75th percentiles)● Categorical variables:o Sample size (n) and percentage non-missingo Count and percentage by category (distribution)

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

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

Unknown