Neuropsychiatric Adverse Events of Abiraterone Acetate and Enzalutamide: Meta-analysis of Randomized Clinical Trials with Real World Reporting Patterns from Eudravigilance

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Study Finalised

Administrative details

EU PAS number

EUPAS35920

Study ID

35921

DARWIN EU® study

No

Study countries

Spain

Study status

Finalised

Research institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

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Primary lead investigator

Maria Paola Moreno Perez

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/02/2017

Study start date
Actual: 01/02/2017

Date of final study report
Actual: 27/02/2018

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Meta-analysis on the incidence of neuropsychiatric adverse events associated with abiraterone+prednisone and enzalutamide observed in clinical trials and analysis of neuropsychiatric suspected adverse drug reactions reported in EudraVigilance for AAP and ENZ.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

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

ABIRATERONE ACETATE

ENZALUTAMIDE

Medical condition to be studied

Prostate cancer

Population studied

Short description of the study population

Patients treated with abiraterone+prednisone and enzalutamide.

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

12.000

Study design details

Outcomes

Meta-analysis on the incidence of neuropsychiatric adverse events associated with abiraterone+prednisone and enzalutamide observed in clinical trials. And analysis of neuropsychiatric suspected adverse drug reactions reported in EudraVigilance for abiraterone+prednisone (AAP) and enzalutamide (ENZ)

Data analysis plan

Meta-analysis was performed to estimate the pooled relative risk of neuropsychiatric adverse events (as listed in each clinical trial: COU-AA-302, COU-AA-301, Prevail and AFFIRM studies) for AAP vs control group and ENZ vs control group. The analyses were conducted using the Mantel–Haenszel fixed-effects model to obtain the average effect and the distribution of relative risk estimates. EudraVigilance: all reports have the same layout, data elements and functionalities. The figure displayed online is always a running total of serious/non-serious spontaneous cases reported in EEA countries. Each individual case in EudraVigilance refers generally to a single patient and it is composed of at least one report, called the initial report, which might be complemented by follow-up reports.

Data management

Data sources

Data source(s), other

EudraVigilance

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

No