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

First published: 22/06/2020

Last updated: 02/04/2024

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

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Maria Paola Moreno Perez RA-RNDUS-ClnclTrlsEU@its.jnj.com

Study contact

RA-RNDUS-ClnclTrlsEU@its.jnj.com

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

12000

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

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), 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