Pharmaco-epidemiologic study on occurrence of adverse events

First published: 03/08/2015

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10402

Study ID

28445

DARWIN EU® study

No

Study countries

☐ France

Study description

Effentora® is an oral, rapidly dissolving opioid tablet indicated for the treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. Following centralized

approval of Effentora®, the Sponsor has conducted a post-marketing study of Effentora® as part of the Risk Management Plan.The primary objective of this study was to estimate the rates of AEs occuring during Effentora® treatment, over the first 3 months following initiation, in a real-life setting. The secondary objectives of the study were: a) to describe Effentora® usage, b) to describe the characteristics of "primary care" population, c) to evaluate the effectiveness of Effentora® in treating pain, d) to evaluate physician and patient satisfaction with the educational brochures that are part of the EU RMP.The study was designed as a prospective, multicenter, longitudinal cohort of Effentora®-naive patients in France during 2013-2014. Specialist physicians and general practitioners were contacted and invited to particiate in the study. Inclusion criteria for patients were the following: a) patients naive to Effentora® treatment, b) patients about to start a titration with Effentora®, c) patients who agreed to particpate in the study and provided a signed Informed Consent form. Patients were excluded from the study if they filled any of the following conditions a) patients under legal guardianship, b) patinets unable or unwilling to complete the AE diary or the patient questionnaire, or patients who did not have a caregiver able to complete the AE diary for him/her, c) patients participating in a clinical trial at the time of study inclusion. Data were collected from patients and physicians and included physicians' and patients' demographics and reason for non-participation, medical history, aetiology of pain, opioid use and abuse, AEs, treatment effectiveness, performance status and satisfaction with educational brochure.

Study status

Finalised

Research institutions and networks

Institutions

ICON Commercialisation & Outcomes

☐ Germany

☐ Ireland

First published: 19/03/2010

Last updated: 05/07/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sigal Kaplan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/06/2012

Actual: 13/12/2012

Study start date

Planned: 01/10/2012

Actual: 28/01/2013

Data analysis start date

Planned: 31/01/2014

Actual: 30/05/2014

Date of final study report

Planned: 30/09/2014

Actual: 30/01/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To estimate rates of AEs occurring during treatment initiation, titration and stabilisation of Effentora, over the first 3 months following initiation, in a real-life setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

EFFENTORA

Population studied

Short description of the study population

a) Patients naive to Effentora® treatment;

b) patients about to start a titration with Effentora®;

c) patients who agreed to particpate in the study and provided a signed Informed Consent form

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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)

Estimated number of subjects

90

Study design details

Outcomes

Rate of AEs in Effentora patients, during the first 3 months of treatment, Effentora treatment effectiviness.Physician and patient satisfaction with educational brochures

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Data analysis plan

The prevalence of an AE was the proportion of patients reporting this AE at a specified time point among the total population. The incidence rate of an AE was the number of new cases in a population at risk in a given timeperiod. Descriptive statistics were used to evaluate all the pertinent variables collected. Tables were stratified where appropriate. Results were stratified to account for factors that may have affected the reporting of AEs (age, pain ateiology, type of

pain, concomitant medication, physician specialty).

Documents

Study results

Gavrielov-Yusim2018- KAPLAN- Challenges of PASS- Lessons learned and results of fentanyl.pdf(318.42 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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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