A Multicentre, Non-interventional, Prospective, Observational Drug Utilisation Study of Ayendi Nasal Spray Prescribed as Treatment in Emergency Departments in the United Kingdom (UK) (DIAPASS)

First published: 14/10/2016

Last updated: 12/11/2019

Study | Finalised

Administrative details

EU PAS number

EUPAS15371

Study ID

32276

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This post-authorisation safety study (PASS) was requested by MHRA to evaluate the practical usage of the product, Ayendi, as a treatment in the Emergency Department. The study will assess the patterns of use particularly in relation to aspects that may have an impact on the safety of the product (e.g. co-medication including other opioids, medication errors). The study will also assess the effectiveness of risk minimisation activities.

Study status

Finalised

Research institutions and networks

Institutions

Southmead Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

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Study contact

deborah.roberts@therakind.com

Primary lead investigator

Jason Kendal

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/04/2013

Actual: 04/08/2016

Study start date

Planned: 01/12/2016

Actual: 11/01/2017

Data analysis start date

Planned: 30/01/2019

Actual: 28/03/2019

Date of interim report, if expected

Planned: 01/06/2016

Actual: 25/04/2018

Date of final study report

Planned: 01/09/2019

Actual: 04/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Wockhardt (UK) Limited

Study protocol

DIA003_DIAPASS Protocol_V3.0 23-11-2016_signed.pdf (2.28 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

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:

Primary data collection

Main study objective:

To evaluate the practical usage of Ayendi Nasal Spray as a treatment post marketing in UK EDs.The study will assess patterns of drug utilisation with respect to aspects that may have an impact on its safety (e.g. co-medication including other opioids, medication errors) and evaluate the effectiveness of risk minimisation activities.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-only, prospective study

Study drug and medical condition

Medicinal product name, other

Ayendi

Population studied

Short description of the study population

Any patient who has been prescribed Ayendi as part of routine treatment in the ED.

To be eligible for inclusion into this study the subjects must fulfil all of the following criteria:

1. Patient has been administered Ayendi Nasal Spray by the attending ED Healthcare Professional as part of ED treatment

2. Parent(s)/legal guardian/adult patient (whichever is applicable) must be able and willing to provide written informed consent before the patient is discharged from the ED

3. Where possible, child patients should assent to allow their data to be used for the study

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Age groups

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

Estimated number of subjects

400

Study design details

Outcomes

To determine the rates of:Doses given (mg/kg) which deviate from the posology as written in the SmPC.Previous opioid usage immediately prior to Ayendi (%), Administration Time (pre-arrival at hospital, if appropriate), Dose Prescribed (mg/kg) vs Dose Given (mg/kg), Product strength and Number of sprays given, Diagnosis Ayendi prescribed for (and % off-label indications), Participating ED practice setting (%), Administrator (%), Concomitant medication, Patient demographics (including patients not within the SmPC-defined categories), Adverse events (%)

Data analysis plan

A statistical analysis plan (SAP) will be developed by a qualified statistician and analysis will be performed according to this document. The SAP will specifically include details of how all: Analysis Populations, Demographic and Baseline Characteristics, Completion and Discontinuation information, Medication details and All Analyses (rate of incorrect dosing, rate of previous opioid usage immediately prior to Ayendi, time of dosing, product strength and number of sprays, indication, ED practice setting, administrator, concomitant medication, and adverse events) will be classified and described. The sample size chosen for the study is considered appropriate based on previous experience. This is an observational study of patients receiving prescribed Ayendi in a UK Hospital Emergency Department. The sample size will have sufficient power to estimate both the rate of incorrect dosing and use in association with other opioids.

Documents

Study results

Summary of DIA003_DIAPASS_Final_Clinical Study Report v1.0 04-11-19.pdf (105.95 KB)

Study, other information

Ayendi PASS AR 04082016.pdf (609.29 KB)

Data management

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

No