Encruse Ellipta Drug Use Investigation (201450)

First published: 09/07/2015

Last updated: 23/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10224

Study ID

42111

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This investigation will be conducted to collect and evaluate information regarding the safety and efficacy of Encruse ELLIPTA under the actual post-marketing use conditions of the product.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Multiple centres: 200 centres are involved in the study

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/02/2014

Actual: 24/02/2014

Study start date
Planned: 30/11/2015

Actual: 06/04/2016

Date of final study report
Planned: 30/09/2019

Actual: 06/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-201450-protocol-redact.pdf(194.31 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

This investigation will be conducted to collect and evaluate information regarding the safety and efficacy of Encruse ELLIPTA under the actual post-marketing use conditions of the product.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non interventional, Observational Post Marketing Surveillance under actual drug use condition.

Study drug and medical condition

Name of medicine, other

Encruse ELLIPTA

Population studied

Short description of the study population

This study was conducted in patients who were first prescribed Encruse for the approved indication, “relief of symptoms of obstructive airway disorder due to COPD (chronic bronchitis and emphysema)”.

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)

Special population of interest

Hepatic impaired

Other

Pregnant women

Renal impaired

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

1000

Study design details

Outcomes

Information regarding the safety and efficacy of Encruse ELLIPTA under the actual post-marketing use conditions of the product.

Data analysis plan

Items related to patient dispositionPatient demographic and baseline characteristicsItems related to safetyItems related to efficacy

Documents

Study results

gsk-201450-clinical-study-report-redact.pdf(1.68 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Electronic data capture (EDC) system

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