An open label, multi-centre, post marketing surveillance (PMS) to monitor the safety and efficacy of INCRUSE administered in Korean subjects with chronic obstructive pulmonary disease (COPD) in usual practice (205163)

First published: 30/08/2016

Last updated: 23/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14947

Study ID

40153

DARWIN EU® study

No

Study countries

Korea, Republic of

Study description

An open label, multi-centre, post marketing surveillance (PMS) to monitor the safety and effectiveness of Incruse administered in Korean subjects with chronic obstructive pulmonary disease (COPD) in usual practice

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Je-Ju National University Hospital Je-Ju, Korea

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: 13/10/2015

Actual: 13/10/2015

Study start date

Planned: 31/08/2016

Actual: 23/08/2016

Date of final study report

Planned: 09/10/2020

Actual: 03/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-205163-protocol-redact.pdf (402.67 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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:

Combined primary data collection and secondary use of data

Main study objective:

To collect safety and effectiveness data of Incruse in Korean COPD patients.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Open-label, single arm, multi-centre post marketing surveillance (PMS). No comparator cohort will be included in this study

Study drug and medical condition

Medicinal product name

INCRUSE ELLIPTA

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

UMECLIDINIUM BROMIDE

Population studied

Short description of the study population

Korean subjects with chronic obstructive pulmonary disease (COPD) in usual practice.

Inclusion criteria

All subjects must satisfy the following criteria

- Adult subjects (19 years and older) who have chronic obstructive pulmonary disease (COPD) -Pulmonary Function Test: Post bronchodilator, FEV1/FVC < 0.7
- Subjects who will administer INCRUSE according to locally approved prescribing information

Exclusion criteria

- Subject who has medical history of hypersensitivity to the active substances or main substances or atropine derivative(i.e. ipratropium,tiotropium, oxitropium, glycopyrronium, aclidinium)
- Subject with severe hypersensitivity to milk proteins
- Subject with hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucosegalactose malabsorption

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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)

Special population of interest

Hepatic impaired

Pregnant women

Renal impaired

Estimated number of subjects

600

Study design details

Outcomes

Primary objective is to monitor adverse events, including unexpected adverse events and/or serious adverse events, reported after administrating at least 1 dose of Incruse.- Minimum of one follow-up visit after administration of Incruse in order to assess safety, Secondary objective is to monitor effectiveness after administrating Incruse, as determined by post BD FEV1 on Treatment Week 24.- Minimum 24 weeks follow-up after administrating Incruse for effectiveness

Data analysis plan

Safety analyses will be based on the population, defined as subjects who receive at least one dose of the Incruse and completed at least one safety assessment. In general, data summaries will be presented overall and by the subgroups of interest. Baseline characteristics will be summarized using descriptive statistics.The number and percentage of subjects reporting adverse event after administration of Incruse will be tabulated. Cases with serious adverse events and/or unexpected adverse drug reactions will be described in detail. The distribution of adverse events will be tabulated. The percentage of subjects reporting adverse events will be analyzed using Chi-square test or Fisher’s exact test stratified by potential confounding factors for subgroup analysis.The percentage of subjects reporting adverse events among specific population e,g. the elderly will be tabulated respectively. The difference of the incidence of adverse events by each factor will be analyzed.

Documents

Study results

gsk-205163-clinical-study-report-redact.pdf (5.41 MB)

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)

Electronic healthcare records (EHR)

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