A Cross-sectional Study to Evaluate the Effectiveness of the Colobreathe Risk Minimisation Educational Programme Among Healthcare Professionals and Patients

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Study Finalised

Administrative details

EU PAS number

EUPAS12030

Study ID

34147

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Denmark

- [ ] France
- [ ] Germany
- [ ] Netherlands
- [ ] United Kingdom

Study description

Colobreathe, authorised in Europe in 2012 through a centralized procedure, is indicated for the management of chronic pulmonary infections due to P. aeruginosa in patients with CF aged 6 years and older. Colobreathe was approved with a requirement for additional risk minimisation measures, specifically, that healthcare professionals (HCPs) and patients are provided with educational material containing information on the need to comply with treatment, instructions on how to use the product (capsules and Turbospin inhaler device), and information on side effects. Educational material has been developed and disseminated in Europe to inform HCPs and patients of important information on the safe use of Colobreathe. This study is being conducted to assess the effectiveness of the educational material among HCPs who prescribe or administer, and patients who use, Colobreathe in Europe. The proposed study utilises a cross-sectional survey study design.

Study status

Finalised

Research institutions and networks

Institutions

Teva B.V.

Contact details

Study institution contact

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Study contact

terri.madison@iconplc.com

Primary lead investigator

Terri Madison

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/06/2015

Actual: 26/10/2015

Study start date

Planned: 16/09/2016

Actual: 28/09/2016

Data analysis start date

Planned: 03/04/2018

Actual: 25/04/2018

Date of final study report

Planned: 31/08/2018

Actual: 02/08/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Forest Laboratories UK Limited, Teva B.V.

Regulatory

Was the study required by a regulatory body?

No

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:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The overall objective of this study is to evaluate process indicators of the effectiveness of the risk minimisation educational material implemented in the EU for Colobreathe, specifically, knowledge rates, and measures of distribution and use of, the Colobreathe RMM educational material.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

COLOBREATHE

Population studied

Short description of the study population

Healthcare professionals (HCPs) who have prescribed or administered Colobreathe within the 12 months prior to completing the survey, and patients (or their caregivers) who have received Colobreathe within the 6 months prior to completing the survey.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

300

Study design details

Outcomes

Knowledge rates of information included in the Colobreathe RMM educational material. Measures of distribution and use of the Colobreathe RMM educational material.

Data analysis plan

The primary analysis population will include all HCPs and patients/caregivers who have completed the survey. The primary criteria are the respondents' knowledge rates across each of the key risk minimisation educational messages for Colobreathe. Other criteria are measures of distribution and use of educational material.Knowledge rates for each of the key risk minimisation educational messages for Colobreathe will be calculated with 95% two-sided CI. Knowledge rates may also be reported by relevant subgroups such as country and recruitment method.

Documents

Study publications

Kaplan S, Patino O, Rainville C, Madison T. Assessment of Colistimethate Sodium…

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

Cross-sectional survey study conducted in HCPs who have prescribed or administered Colobreathe within the 12 months prior to completing the survey, and in patients (or their caregivers) who have received Colobreathe within the 6 months prior to completing the survey

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