An Open-label Observational Safety Study of Colobreathe® (colistimethate sodium dry powder for inhalation) Compared with Other Inhaled Anti-pseudomonal Antibiotics in Cystic Fibrosis Patients Using Cystic Fibrosis Registries

First published: 27/11/2016

Last updated: 10/03/2020

Study Finalised

Administrative details

EU PAS number

EUPAS16395

Study ID

34038

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This observational, registry-based safety study is being conducted pursuant to a post-authorisation commitment with EMA. The study has been designed to evaluate the long-term safety of Colobreathe used in patients with cystic fibrosis with P. aeruginosa infection of the lungs, compared with other inhaled anti-pseudomonal antibiotics. Particular attention will be paid to adverse events (AEs) of cough/productive cough, chest discomfort/chest pain, wheezing/bronchospasm, dyspnoea, dysphonia, lower respiratory tract infection, and taste abnormality (dysgeusia) occurring in the first 90 days of treatment. The study population includes patients enrolled in the UK cystic fibrosis (CF) registry database who are prescribed Colobreathe (treated group) versus matched patients in the CF registry database not treated with Colobreathe but taking other inhaled antibiotic treatments (Comparator-treated). Patients prescribed Colobreathe and matched patients receiving other inhaled antibiotic therapies will be followed-up for up to 5 years.

Study status

Finalised

Research institutions and networks

Institutions

Cystic Fibrosis Trust

United Kingdom

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Institution | Not-for-profit

Contact details

Study institution contact

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Primary lead investigator

Diana Bilton

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/10/2014

Actual: 21/10/2014

Study start date

Planned: 01/01/2014

Actual: 01/01/2014

Date of interim report, if expected

Actual: 30/06/2018

Date of final study report
Planned: 30/06/2019

Actual: 07/08/2019

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

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to evaluate the long-term safety of Colobreathe used in patients with cystic fibrosis with P. aeruginosa infection of the lungs, compared with other inhaled anti-pseudomonal antibiotics.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

COLOBREATHE

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

COLISTIMETHATE SODIUM

Population studied

Short description of the study population

Patients enrolled in the UK cystic fibrosis (CF) registry database who were prescribed Colobreathe (treated group) and matched patients in the CF registry database not treated with Colobreathe but taking other inhaled antibiotic treatments (Comparator-treated).

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

11.400

Study design details

Outcomes

Annual rates of all adverse events (AEs) reported for the Colobreathe-treated and matched, comparator-treated patients, 1. Reasons for discontinuing treatment2. AEs of special interest (cough/productive cough, chest discomfort/chest pain, wheezing/bronchospasm, dysphonia, dyspnoea, lower respiratory tract infection, and taste abnormality dysgeusia) in the first 90 days of treatment3. Off-label use4. PA exacerbations

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Data analysis plan

At each interim (6-month) data review, descriptive analyses will be conducted to describe the demographic features of patients, incidence rates of AEs, and the frequency and reasons for discontinuing treatment.Interim analyses will include comparative analyses. A negative binomial model will be used to compare the annualized rate of any AEs between Colobreathe-treated and comparator-treated groups. Model estimates will be adjusted for propensity score.

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)

Disease registry

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