Incidence of oral thrush in COPD patients prescribed ICS as part of ICS/LABA therapy

First published: 11/03/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12762

Study ID

14064

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A historical cohort, UK database study in patients with COPD comparing the incidence of oral thrush in those prescribed ICS as part of fixed-dose combination ICS/LABA therapies, with that in patients prescribed long-acting

bronchodilator therapies without ICS

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution **Educational Institution** **Laboratory/Research/Testing facility**

ENCePP partner

Contact details

Study institution contact

David Price dprice@rirl.org

Study contact

dprice@rirl.org

Primary lead investigator

Lucy Wood

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/02/2015

Actual: 05/03/2015

Study start date
Planned: 07/04/2015

Actual: 07/04/2015

Data analysis start date
Planned: 07/04/2015

Actual: 07/04/2015

Date of interim report, if expected
Planned: 12/05/2015

Actual: 12/05/2015

Date of final study report
Planned: 30/05/2016

Actual: 29/06/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TEVA Pharmaceutical Industries

Study protocol

150407_R00115_Oral_thrush_ICS_LABA_protocol_V1.5b.pdf (671.08 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Observational study

Data collection methods:

Secondary use of data

Main study objective:

The aim of the study is two-fold: first, to investigate whether there is an association between ICS use as part of an FDC ICS/LABA and oral thrush in patients with COPD (Phase 1), and second, to assess whether this potential relationship between FDC ICS/LABA use and oral thrush is modulated by the ICS drug and dose within the prescribed FDC device (Phase 2).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Symbicort, Seretide

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Chronic obstructive pulmonary disease (COPD) patients aged ≥ 40 years at first prescription (i.e. index date) for fixed-dose combination (FDC) inhaled corticosteroid (ICS)/ long-acting β2 agonist (LABA), or first prescription for or addition of long-acting bronchodilator, at least 2 years of continuous practice data (1 year of baseline and 1 year of outcome data), and ≥ 2 prescriptions for FDC ICS/LABA or long-acting bronchodilator during the outcome period (including the index date prescription).

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

Other

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

22808

Study design details

Outcomes

Incidence of oral thrush, defined as the proportion of patients with a diagnosis and/or prescribed medication for treating oral thrush within the outcome period.

Data analysis plan

Statistically significant results will be defined as $p<0.05$ and trends as $0.05 \leq p<0.10$. Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and for each matched cohort. All two-way comparisons of the primary outcome between treatment arms will be analysed using conditional logistic regression. Results will be reported as both: number (%) of patients diagnosed/prescribed therapy for oral thrush, and the odds ratio (95% CI), crude and adjusted for baseline predictors/confounders. The 5% level of significance will be used (two-tailed test).

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 source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

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