# Characteristics of patients initiating Spiriva Respimat in Asthma in the UK: a cross-sectional study based on the Clinical Practice Research Datalink

**First published:** 12/10/2018

**Last updated:** 24/09/2026

Study Finalised

## Administrative details

**EU PAS number**

EUPAS25682

**Study ID**

25683

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

This study is a cross-sectional, non-interventional study based on existing data (NISed). The UK CPRD data will be used to assess the characteristics of asthma patients who were prescribed ICS/LABA FDC before the index date and who initiated Spiriva Respimat, or received a higher dose of ICS/LABA FDC, or initiated LTRA, or switched to a new ICS/LABA FDC in the UK during the study period (September 2014-December 2017) enabling to assess potential channeling of prescribing to different patient populations.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Boehringer Ingelheim

**First published:** 01/02/2024

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**Institution**

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Jennifer Quint

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/09/2018

Actual: 01/09/2018

**Study start date**

Planned: 23/10/2018

Actual: 05/03/2019

**Date of final study report**

Planned: 31/03/2019

Actual: 20/10/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## Study protocol

0205-0537_CTP.pdf (631.16 KB)

0205-0537_protocol_redacted.pdf (634.02 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

## Other study registration identification numbers and links

0205-0537

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

This study is a cross-sectional, non-interventional study based on existing data (NISed). The UK CPRD data will be used to assess the characteristics of asthma patients who were prescribed ICS/LABA FDC before the index date and who initiated Spiriva Respimat, or received a higher dose of ICS/LABA.

**Main study objective:**

The main objective of the study is to describe the clinical and socio-demographic characteristics of asthma patients prior to the initiation of Spiriva Respimat for the treatment of Asthma within a general clinical population using the Clinical Practice Research Database (CPRD).

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medicinal product name**

SPIRIVA RESPIMAT

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**Medicinal product name, other**

ICS/LABA, LTRA

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

TIOTROPIUM BROMIDE

**Anatomical Therapeutic Chemical (ATC) code**

(R03BB04) tiotropium bromide

tiotropium bromide

**Medical condition to be studied**

Asthma

## Population studied

**Short description of the study population**

The study population will be asthmatic patients who were prescribed ICS/LABA FDC before the index date and who initiated Spiriva Respimat, or received a higher dose of ICS/LABA FDC, or initiated LTRA, or switched to a new ICS/LABA FDC from the previous ICS/LABA FDC in the UK during the study period (September, 2014-December 31, 2017).

**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)

**Estimated number of subjects**

500

## Study design details

**Comparators**

Asthma patients who initiated a higher dose of ICS/LABA FDC, or LTRA, or alternatively those who switched from the previous ICS/LABA FDC to a new ICS/LABA FDC (for the secondary objective).

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**Outcomes**

The primary outcome is whether patient has Cardiac arrhythmias on the index date or in the year prior to the index date. The secondary outcome is whether patient has Cardiac failure on the index date or in the year prior to the index date.

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**Data analysis plan**

Patient characteristics will be tabulated and summarized for all new users of Spiriva Respimat. In addition, patient characteristics will be tabulated for the patients that initiated or switched to the other available treatments. Patient characteristics will be compared among patients who initiated Spiriva Respimat and patients in other treatment groups. Analyses will be conducted in unmatched cohorts and differences between Spiriva Restinmat and each of the other exposure groups will be assessed using absolute standardized differences (ASD),where an ASD of at least 10% will be considered a meaningful difference.

## Documents

**Study results**

0205-0537_Synopsis.pdf (876.01 KB)

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# 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)

# 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