A real-world non-interventional study to assess patient satisfaction with and preference for re-usable Respimat Soft Mist inhaler in patients with chronic obstructive pulmonary disease

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Study Finalised

Administrative details

EU PAS number

EUPAS30293

Study ID

36207

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark

- [ ] Finland
- [ ] Germany
- [ ] Netherlands
- [ ] Norway

Study description

A real-world non-interventional study to assess patient satisfaction with inhaler attributes of the re-usable Respimat® Soft MistTM Inhaler (SMI) in adult patients with chronic obstructive pulmonary disease (COPD),including patients who are Respimat SMI-experienced and Respimat SMI-naïve. This study also aims to examine patient preference for the re-usable Respimat SMI compared to the disposable Respimat SMI in Respimat SMI-experienced patients switching from a disposable toa re-usable Respimat SMI product at study entry

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Multiple centres: 22 centres are involved in the study

Contact details

Study institution contact

Asparuh Gardev asparuh.gardev@boehringer-ingelheim.com

Study contact

asparuh.gardev@boehringer-ingelheim.com

Primary lead investigator

Michael Dreher

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/09/2019

Actual: 17/09/2019

Study start date

Planned: 30/09/2019

Actual: 07/10/2019

Data analysis start date
Planned: 12/03/2020

Actual: 06/03/2020

Date of final study report
Planned: 29/06/2020

Actual: 22/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim International GmbH

Study protocol

1237-0097-bi-respimat-protocol-final-1-0-11 Jun 2019_R19Jun2019-clean.pdf
(1.81 MB)

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

Study type:

Non-interventional study

Scope of the study:

Other

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

Patient satisfaction with inhaler attributes

Data collection methods:

Primary data collection

Main study objective:

The primary objective of the study is to assess patientsatisfaction with the re-usable Respimat SMI, assessingthe mean total score of the validated Patient Satisfactionand Preference Questionnaire (PASAPQ) at study end.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

The study population will include patients (aged 40 and above) with COPD, who are residing in one of the target countries and follow the routine clinical practice of the participant sites. Patients should be prescribed a re-usable Respimat SMI product, during the study period, in the course of standard medical practice. Patients must be able to inhale the medication in a competent manner from the Respimat SMI according to the Clinical investigator's judgement, which will be recorded in the electronic case report form (eCRF) as per standard clinical practice.

Inclusion criteria:

Patients fulfilling all the following inclusion criteria will be eligible for participation in the study:

- Provision of signed informed consent prior to study data collection
- Patient with COPD aged 40 years or older
- Patient prescribed (or already receiving the disposable Respimat SMI and switched to) 1 of the following re-usable Respimat SMI products per the standard clinical practice:

Spiriva 2.5 microgram inhalation solution, Striverdi 2.5 microgram inhalation solution or Spiolto 2.5 microgram / 2.5 microgram inhalation solution

- Patient unlikely to change their Respimat therapy during the observation period (in the opinion of the investigator)

Exclusion criteria:

Patients fulfilling any of the following exclusion criteria will not be eligible for participation in the study:

- Patient using a disposable Respimat SMI product during the study period, after study entry
- Patient who have had a severe COPD exacerbation requiring hospitalisation in the immediate 3 months prior to study entry
- Patient participating in a clinical trial or any other non-interventional study of a

drug or inhaler at the time of enrolment
- Visual, cognitive, motor or health impairment that, as judged by the investigator, may cause concern regarding the patient's ability to complete the questionnaires
- Patient not fluent and literate in one of the main languages of the country

Age groups

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

250

Study design details

Outcomes

The primary objective of the study is to assess patientsatisfaction with the re-usable Respimat SMI, assessingthe mean total score of the validated Patient Satisfactionand Preference Questionnaire (PASAPQ) at study end. 1. To examine the individual domains of the PASAPQ:total performance score, total convenience score, the overall satisfaction question and the question

onwillingness to continue with inhaler at study end2. To examine ease of handling of the re-usableRespimat SMI at study end

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Data analysis plan

The total PASAPQ and the domain scores (total performance score, totalconvenience score, overall patient satisfaction score and the rating ofwillingness to continue with the inhaler) will be summarised usingdescriptive statistics for continuous variables.The difference in the mean total PASAPQ score between baseline andstudy end, in Respimat SMI-experienced patients switching from adisposable to a re-usable Respimat SMI product at study entry, will becompared using a two-tailed paired t-test or an appropriate non-parametric test (e.g. Wilcoxon signed ranks test), depending on the distributions of the count / score data.Responses to the questions on the ease of handling of the re-usable Respimat SMI will be summarised using descriptive statistics for categorical or continuous variables, as appropriate.

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

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