SATisfaction and adherence to COPD treatment

First published: 27/05/2016

Last updated: 24/09/2026

Study Finalised

Administrative details

EU PAS number

EUPAS13605

Study ID

13606

DARWIN EU® study

No

Study countries

Italy

Study description

The present study will explore the patients' satisfaction to COPD medical treatment (i.e. pharmacological and not pharmacological treatment) in a clinical real-world setting and how the satisfaction for medical treatment is related to

clinical parameters, quality of life, illness perception and treatment adherence evolution. Moreover health care resource consumption will be observed during the observation period.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Ingelheim Boehringer MEDICABIITALIA@boehringer-ingelheim.com

Study contact

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Primary lead investigator

Ingelheim Boehringer

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 08/09/2015

Actual: 08/09/2015

Study start date
Planned: 25/11/2015

Actual: 25/11/2015

Date of final study report
Planned: 31/12/2017

Actual: 30/08/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer-Ingelheim

Study protocol

1237-0051_clinical-trial-protocol-version-1_Redacted.pdf (715.6 KB)

1237-0051_protocol_redacted.pdf (715.6 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

1237.51

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Healthcare resource utilisation

Other

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

Disease awareness and treatment satisfaction

Data collection methods:

Primary data collection

Study design:

Multi-center, non-interventional (observational), prospective cohort study based mainly on newly-collected data.

Main study objective:

To describe the patients’ satisfaction to COPD medical treatments (by means of the TSQM9) during a 12-month observation period (namely, at enrolment, and after 6 and 12 months) in real- world setting

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

400

Study design details

Setting

20 Italian Pneumology Centres.

Outcomes

Patient Reported Outcomes Questionnaires/scales (filled in by patient or the investigator): Treatment Satisfaction Questionnaire, 9 items (TSQM-9), Brief Illness Perception Questionnaire (B-IPQ), COPD Assessment Test (CAT), Modified Medical Research Council Dyspnea Scale (MMRC), Morisky Medication-Taking Adherence Scale, Awareness structured interview (COPD awareness questionnaire).

Data analysis plan

Descriptive analysis will be means, medians, quantiles, proportions (with their respective 95% confidence intervals and SE when relevant) and contingency tables according to the nature of the variables. As a dispersion measurement the standard deviation and the interquartile range will be calculated.The statistical analysis will be done on all evaluable patients i.e. patients who enter the study without inclusion-exclusion criteria violations and with at least one

TSQM-9 domain score (effectiveness, convenience and global satisfaction) calculated. Patients with missing values will not be excluded from the analysis, their data will not be replaced, frequency of missing data will be given for all analyzed variables. Lost to follow up patients will be analyzed until their last available visit.

Documents

Study results

1237-0051_Synopsis.pdf (282.42 KB)

Study publications

https://pubmed.ncbi.nlm.nih.gov/31760881/

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