Boehringer Ingelheim

Observational and Non-Interventional Study (ONIS) using Existing Data Protocol

BI Study Number:	0205-0548
Title:	Hospitalization, mortality rates and costs associated with chronic obstructive pulmonary disease (COPD) in Distrito Federal, Brazil, before and after the change in 2018 state COPD protocol version – Real-world data
NCT number:	NCT06053541
Medicinal product:	*Tiotropium bromide (SPIRIVA® RESPIMAT®)*
Date	**28-May-2021**
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DF COPD Study Protocol

Objective: to investigate potential different patterns on chronic obstructive pulmonary disease (COPD) mortality, hospitalizations, ICU usage rates and costs after the COPD protocol change in Distrito Federal (DF), Brazil, in August 2018, with a substitution of tiotropium in soft mist inhaler to glycopyrronium in dry powder inhaler.

Methods: To analyze DATASUS, Brazilian Ministry of Health Public Database, data from patients ≥ 40 years old hospitalization and mortality rates due to COPD International Classification of Diseases (ICD) listed in the COPD DF Protocol 12 months before the protocol change (MAT 1) and 12 months after (MAT 2).

Table 1: ICD filters, per the DF COPD Protocol[1]:

J41.0	Simple chronic bronchitis
J41.1	Mucopurulent chronic bronchitis
J41.8	Mixed simple and mucopurulent chronic bronchitis
J42	Unspecified chronic bronchitis
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J43.9	Emphysema, unspecified
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.8	Other specified chronic obstructive pulmonary disease
J44.9	Chronic obstructive pulmonary disease, unspecified

On DATASUS, data on DF 40 years old or older population hospitalization and mortality rates filtered by the ICDs listed in Table 1 will be analyzed. The searches generate a LOG in order to ensure methodology. The data will be available on Microsoft Excel.

Table 2: Information Available in the Hospital DataSUS Database (SIH).

DATASUS_COLUMN	DATA	MEANING
UF_ZI	530000	STATE CODE
ANO_CMPT	2013	YEAR
MES_CMPT	1	MONTH
N_AIH	5312100277187	Authorization of Admission Number (13 Numbers) Unique
CEP	71693046	ZIP CODE PATIENT
MUNIC_RES	530160	CITY CODE PATIENT
NASC	19970917	BIRTHDAY PATIENT
SEXO	3	GENDER
UTI_MES_IN	0	UTI USE INDICATION
QT_DIARIAS	0	QTY OF DAYS IN HOSPITAL
PROC_SOLIC	301050074	REQUIRED PROCEDURE COD
PROC_REA	301050074	PROCEDURE EXECUTED NUMBER
VAL_SH	570,9	PROCEDURE VALUE (R$)
VAL_SP	153	PROCEDURE WORKER VALUE (R$)
VAL_TOT	723,9	TOTAL COST VALUE (R$)
VAL_UTI	0	TOTAL COST ICU (R$)
DT_INTER	20121201	ADMISSION DATA
DT_SAIDA	20121231	HOSPITAL DISCHARGE DATA
DIAG_PRINC	J448	ICD CODE DIAGNOSTHIC OF ADMISSION
IDADE	15	AGE
DIAS_PERM	30	NUMBER OF DAYS IN HOSPITAL
MORTE	0	DEATH INDICATION
CNES	2650355	HOSPITAL NATIONAL CODE

The following outcomes will be analyzed:

1. Number of hospital admissions with and without ICU admissions

2. Hospital admission mortality with and without ICU admissions

3. Total costs associated with COPD hospitalizations

4. Infirmary beds (General and ICU beds)

The statistical analyses will be performed with Mann-Whitney test considering a p <0.05 for statistical significance, as the DATASUS generates unpaired data. The collected data will generate an observational, cross-sectional study in the cohort of adult hospitalized COPD patients.

References

1. Governo do Distrito Federal. Protocolo de Atenção à Saúde: TRATAMENTO MEDICAMENTOSO DA DOENÇA PULMONAR OBSTRUTIVA CRÔNICA ESTÁVEL. Available at: http://www.saude.df.gov.br/wp-conteudo/uploads/2020/09/Protocolo-DPOC-SES-DF.pdf Accessed on 19 Feb 2021.