Multinational, multi-database drug utilization study of inhaled NVA237 in Europe (NVA237 DUS)

First published: 26/09/2013

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS4845

Study ID

38226

DARWIN EU® study

No

Study countries

- Denmark
- Italy
- Netherlands
- Spain

United Kingdom

Study description

In the context of the NVA237 marketing authorization application (and it’s multiple marketing authorization applications), the Committee for Medicinal Products for human use (CHMP) recommended conditions for marketing authorization and product information and suggested to conduct a post-authorization drug utilization study.The objectives of this study are to estimate the subpopulation with cardiovascular co-morbidity and to identify patients groups with missing information in the Risk Management Plan.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Società Italiana di Medicina Generale e delle Cure Primarie (SIMG)

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Patient organisation/association

SIDIAP Jordi Gol Spain, Department of Clinical Epidemiology Denmark

Networks

EU-ADR Alliance

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Clinical Disclosure Officer Novartis

Trialandresults.registries@novartis.com

Study contact

Trialandresults.registries@novartis.com

Primary lead investigator

Clinical Disclosure Officer Novartis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/03/2013

Actual: 05/07/2013

Study start date

Planned: 01/11/2012

Actual: 01/11/2012

Data analysis start date

Planned: 27/09/2013

Date of interim report, if expected

Planned: 06/12/2013

Date of final study report

Planned: 30/11/2015

Actual: 28/04/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

NVA237A2401T-v02--protocol_Redacted.pdf (847.73 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

EU RMP category 3 (required)

Other study registration identification numbers and links

CNVA237A2401T

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

1. To determine the proportion of patients using NVA237 who also have cardiovascular or cerebrovascular co-morbidities 2. To determine the proportion of patients using NVA237 who have missing information as per RMP or high risk treatment conditions: 2a) A history of the various conditions2b) Off-label use. 2c) Uninterrupted use for more than one year.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Exploratory, descriptive study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03BB06) glycopyrronium bromide

glycopyrronium bromide

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

From the databases containing available NVA237-exposure data from November 2012 onwards, a cohort of patients with a first-time prescription or dispensation of NVA237 was selected. Patients without one year of database history before the first prescription of NVA237 were excluded from the study. No further exclusion criteria were applied.

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

Hepatic impaired

Other

Pregnant women

Renal impaired

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

3000

Study design details

Data analysis plan

Descriptive statistics will be used. Categorical data will be presented as counts (n) and proportions (%) along with (95% confidence intervals). For continuous data, the number of observations (n), mean, standard deviation, median (with interquartile range) will be presented. Yearly progress reports will be prepared containing country specific data. Only for the final analysis (end of study), pooled data will be presented.

Documents

Study results

NVA237A2401T-Redacted-Final-Study-Report.pdf (3.07 MB)

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)

THIN® (The Health Improvement Network®)

Danish registries (access/analysis)

Health Search/IQVIA Health Longitudinal Patient Database

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

Drug dispensing/prescription data

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