Outpatient care with long-acting bronchodilators: COPD Register in Germany (DACCORD)

First published: 27/06/2013

Last updated: 23/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS4207

Study ID

44845

DARWIN EU® study

No

Study countries

Germany

Study description

The DACCORD registry aims to close the apparent gap between populations in clinical trials and daily live by evaluating different treatment approaches in COPD with respect to their efficacy and tolerability and their impact on patient-related outcomes. DACCORD is a prospective observational German registry since November 2012, evaluating data of 16,000 COPD patients from approximately 700 sites distributed in three different cohorts. To guarantee the best selection under the conditions of a non-interventional study, patients have to fulfill the criteria for recruitment to the German COPD DMP (Disease Management Program), implemented by the statutory health insurances. The primary objective is to evaluate diagnosis and therapy of outpatient-treated COPD patients under special consideration of individual treatment success, determined by therapy adherence, symptoms and patient-reported outcomes. Among the secondary objectives are the characteristics of exacerbations and COPD progression, measured by lung function and CAT (COPD Assessment Test) questionnaire

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 700 centres are involved in the study

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

Trialandresults.registries@novartis.com

Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/06/2012

Study start date

Actual: 05/11/2012

Data analysis start date

Planned: 01/06/2015

Actual: 14/03/2021

Date of interim report, if expected
Planned: 01/11/2015

Actual: 25/01/2019

Date of final study report
Planned: 01/02/2022

Actual: 27/10/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals

Study protocol

DACCORD Studie 02 08 2012_v0 0final_EN_Redacted.pdf (430.39 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

CNVA237ADE01

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The DACCORD registry will be able to provide insights into the real world efficacy and safety of long-acting bronchodilators in the management of COPD.

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

All consecutive patients with COPD should be considered for study enrolment in line with the inclusion criteria if they are receiving established antiobstructive drugs or glycopyrronium bromide after undergoing treatment modification or being started on treatment. In all events the treating doctor must make the therapeutic decision prior to the patient being documented in the Register.
The resulting inclusion criteria are:

• Written consent of the patient to participation in the study
• Age: ≥ 40 years
• Diagnosis of COPD by a doctor
• Initiation or modification of pharmacological COPD treatment at the start of the study (visit 0)
• Recruitment to the COPD DMP or fulfilment of the DMP inclusion criteria

Enrolled patients should be monitored for at least two years, hence foreseeable difficulties with following up on a patient entail an exclusion criterion.
The following additional exclusion criteria are to be noted:

• Recruitment to DMP Asthma bronchiale

• Ongoing participation in a randomised clinical trial

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)

Special population of interest

Other

Special population of interest, other

Chronic obstructive pulmonary disease (COPD) patients

Estimated number of subjects

16000

Study design details

Outcomes

The primary objective is to describe the diagnosis and treatment of patients with COPD while paying special attention to the individual treatment outcome, as measured by treatment compliance, symptoms and patient-related endpoints. The following therapies will be observed: glycopyrronium bromide therapy versus an established Disease Management Program (DMP) versus therapy with LABA/LA, Among the secondary objectives are the characteristics of exacerbations (rate, severity and time to first) and COPD progression, measured by lung function and CAT (COPD Assessment Test) questionnaire.

Data analysis plan

Systematic group differences with respect to prognostic factors must be anticipated in a non-randomized study, leading to distortion from confounding. In order to still permit comparisons between the two study arms, propensity score stratification will be performed. A detailed description will be provided in a separately written statistical analysis plan (SAP), the risk factors to be included therein are still to be defined. The all-documented patient group covers all patients with at least one entry in the eCRF. The analyses will be differentiated, modeled on randomized clinical trials using the ITT (intend-to-treat) and PP (per-protocol) population. All the parameters recorded will be analyzed descriptively. The qualitative data will be analyzed using absolute values and percentages, and the continuous variables presented in in a final statistical report using median and quartile values.

Documents

Study results

CNVA237ADE01_DACCORD_CSR_C1&2_25Jan2019_combined_Redacted.pdf (1.27 MB)

CNVA237ADE01_final study report_C3_DACCORD_combined_27Oct2021_Redacted.pdf (1.06 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 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