Description of the pharmaceutical treatment advice in patients with respiratory symptoms in primary care setting (DEPART)

First published: 01/07/2020

Last updated: 30/03/2021

Study Ongoing

Administrative details

EU PAS number

EUPAS36118

Study ID

40357

DARWIN EU® study

No

Study countries

Netherlands

Study description

In the Netherlands, 60% to 80% of all chronic obstructive lung diseases are treated by the general practitioner (GP). Misdiagnosis, underdiagnosis, not indicated treatment prescriptions are common. The asthma/chronic obstructive pulmonary disease (COPD) (AC) service was implemented in the northern part of the Netherlands to support GPs by providing a working diagnosis and treatment advice by the pulmonologists affiliated with the AC service. It is unclear whether these pharmacological recommendations are followed by GPs and whether there are explanatory factors that would explain the deviation from the treatment advice. Therefore, this study aims to investigate the concordance of the pharmacological advices provided by the AC service at the first visit and the patient-reported inhalation medication prescribed by the GP at visit two. The study population consist of patients (≥18 years) treated in primary care with a working diagnosis COPD, asthma or asthma/COPD overlap as provided by the AC service. Provided pharmacological treatment advice at visit one by the AC-service must be available. Patients will be excluded if no second visit is scheduled and if there is no patient-reported pharmacological information available during visit two. To this end, the percentages of concordance or discordance of the pharmacological treatment advice will be described, multivariate analysis will be performed to gain insight in explanatory differences between the two groups, and multivariate regression analysis will be performed to gain insight in possible predictors of deviation from the provided treatment advice.

Study status

Ongoing

Research institutions and networks

Institutions

General Practitioners Research Institute (GPRI)

Netherlands

First published: 31/08/2022

Last updated: 31/08/2022

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

Janwillem H. Kocks info@gpri.nl

Study contact

info@gpri.nl

Primary lead investigator

Janwillem H. Kocks

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/05/2020

Actual: 08/05/2020

Study start date

Planned: 28/05/2020

Actual: 28/05/2020

Data analysis start date
Planned: 02/07/2020

Date of interim report, if expected
Planned: 17/08/2020

Actual: 17/08/2020

Date of final study report
Planned: 31/08/2021

Sources of funding

- Other

More details on funding

General Practitioners Research Institute

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 type:

Non-interventional study

Main study objective:

Percentages will be used to express the concordance of the pharmacological advices provided by the AC service at the first visit and the patient-reported inhalation medication prescribed by the GP at visit two.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Asthma

Asthma-chronic obstructive pulmonary disease overlap syndrome

Population studied

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)

Estimated number of subjects

19.000

Study design details

Outcomes

Statistical analyses will be performed to gain insight into factors associated with concordance or discordance. In addition, to investigate associations between switching pharmacological treatment, health status, and the number of exacerbations. Regression and (optional) multilevel modeling will be performed to clarify the predictor variables which contribute to refrain from treatment advice

---

Data analysis plan

The primary outcome parameter is percentages that express whether the provided treatment advice is followed by the general practitioner. Differences between the re-referred group and the group visiting the AC service once will be examined. Using several statistical analyses depending on measurement levels. The analysis will be performed to gain insight into possible differences between the concordance and discordance group. Whether or not the provided pharmacological treatment advice is followed serves as the dependent variable. If the p-value is <0.05, the results will be reported as statistically significant. Differences in the number of exacerbations and health status between the concordance group and discordance group will be examined by multivariate analyses. A multiple logistic regression model and (optional) multilevel modeling will be used to model the probability of switching pharmacological treatment between the first visit and the follow-up visit.

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)

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