# 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.

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**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**

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**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

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**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**

19000

## 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

## 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