SADT in COPD and Oscillometry in obstructive airway disease in primary care (SCOOP-study)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000183

Study ID

1000000183

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

The Small Airways are a major site of obstruction in many respiratory diseases, including COPD. More insight into a diagnosis of Small Airways Dysfunction (SAD) in patients with COPD is clinically valuable as it might enable tailored pharmacotherapy. Currently, methods to diagnose SAD in COPD are not standardized and are not available in routine clinical practice. The Small Airways Dysfunction Tool (SADT) was developed to identify patients with asthma and SAD. Initially, the SADT included a comprehensive 63-item questionnaire. The number of items has been reduced to a SADT-asthma (SADT-a) questionnaire and key patient and disease characteristics for it to be feasible and implementable in clinical practice. Although there are many similarities between asthma and COPD, there might be differences in clinical characteristics and responses to small airways dysfunction between the two diseases.
The current study aims to adapt the original 63-item SADT questionnaire for dedicated use in COPD by reducing the number of items, and identifying COPD-SAD-specific items, to enhance its efficiency in identifying SAD when combined with key patient and disease characteristics in individuals with COPD (SADT-c). In addition, a comparison of diagnostic accuracy of spirometry and oscillometry will be made by interpretations by a panel of experts to provide a triage diagnosis. The previously developed machine learning AC/DC tool will be used to explore its diagnostic accuracy using oscillometry and spirometry results. This can contribute to standardizing oscillometry in clinical practice.

Study status

Planned

Research institutions and networks

Institutions

General Practitioners Research Institute (GPRI)

Netherlands

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Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Janwillem Kocks

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2024

Actual: 01/02/2024

Study start date

Planned: 15/06/2024

Data analysis start date
Planned: 01/09/2024

Date of final study report
Planned: 31/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Chiesi Farmaceutici S.p.A.

Study protocol

C1.Research_Protocol_Scoop_v1_19apr2024.pdf (1.37 MB)

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 topic:

Medical procedure

Study type:

Non-interventional study

Scope of the study:

Method development or testing

Data collection methods:

Primary data collection

Study design:

Participants, attending for usual or diagnostic care, will undergo an spirometry and oscillometry test and complete a SADT-c questionnaire. The spirometry and oscillometry reports will be reviewed by a panel of experts (3-5 pulmonologists) for comparison of diagnostic effectiveness.

Main study objective:

The primary objective is to determine whether SADT-c can be used in patients with COPD to detect SAD.

Study Design

Non-interventional study design

Case-only

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Asthma

Asthma-chronic obstructive pulmonary disease overlap syndrome

Population studied

Short description of the study population

The study population for the SCOOP study will consist of patients referred by their General Practitioner (GP) to the Asthma/COPD service. Patients can be referred by their GP when they are suspected to have asthma, Chronic Obstructive Pulmonary Disease (COPD), asthma-COPD overlap (ACO) or when they present with pulmonary symptoms of unknown origin. After referral by the GP, patients will be invited by the Asthma/COPD service. Both patients invited for an initial diagnostic visit or a control visit can participate in the SCOOP study.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

200

Study design details

Setting

The SCOOP study will be integrated in the visits of the Asthma/COPD service for primary care at the study sites. General Practitioners (GPs) can refer individual patients (>18 years of age) who are suspected to have obstructive airway disease (OAD) such as asthma, Chronic Obstructive Pulmonary Disease (COPD), asthma-COPD overlap (ACO) or present with pulmonary symptoms of unknown origin. Visits can be for initial diagnosis of the OAD or for (yearly) follow-up of the disease.

In order to be eligible to participate in this study, a participant must meet all of the following criteria:

• >35 years or older

• Suspected of having COPD, asthma or ACO as indicated by the referring GP OR a previous diagnosis of COPD

A potential participant who meets the following criterium will be excluded from participation in this study:

• Inability to understand and sign the written informed consent form.

Outcomes

Primary objective:

The predictive value of SADT-c for detecting SAD in patients with COPD.

Secondary objectives:

- Predictive value of SADT-a bronze model for SAD in COPD.
- Relative predictive value of SADT-a versus SADT-c for SAD in COPD defined as R5–R20 > ULN.
- Agreement between triage diagnoses from oscillometry and spirometry.
- Relative usability of spirometry and oscillometry.

Exploratory objective:

Diagnostic performance of AC/DC tool compared to expert panel diagnosis.

Data analysis plan

See protocol

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.

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