Defining type 2 asthma phenotypes based on clinical, biological and functional parameters using cluster analysis.

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The main objective is to investigate the heterogeneity of type 2 asthma by identifying phenotypes by means of cluster analysis. Secondary, the clinical interpretation of these clusters is investigated.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON51135

Source
ToetsingOnline

Brief title
The 2CLASS study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma with eosinophilic inflammation, Type 2 asthma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: via onderzoeksbureau longgeneeskunde MST

Intervention

Keyword: Cluster analysis, Phenotype, Type 2 asthma

Outcome measures

Primary outcome

The main endpoint of this study is the formation of type 2 asthma clusters

based on patient and asthma characteristics.

Secondary outcome

Secondary, the found clusters will be compared and clinically interpreted.

Study description

Background summary

Asthma is a common heterogeneous disease characterised by bronchial hyperresponsiveness, airway inflammation and reversible airflow obstruction. The clinical, biological and functional characteristics vary widely between patients.
Type 2 inflammation is reflected by high sputum and/or blood eosinophil levels, an increased fractional of exhaled nitric oxide, and/or allergen mediated asthma. These characteristics are especially under attention since they appear to have predictive value for severe exacerbation and for response to biological treatment. Around 75 percent of difficult to treat asthma patients have at least one of these type 2 asthma characteristics.
Disentangling type 2 asthma by defining phenotypes might result in further optimizing patient tailored treatment and improving quality of life.

Study objective

The main objective is to investigate the heterogeneity of type 2 asthma by identifying phenotypes by means of cluster analysis. Secondary, the clinical interpretation of these clusters is investigated.

Study design

The study will have an observational cross-sectional design. Parameters from demographic data, blood tests, lung function and questionnaires will be used to determine clusters. After assessing the quality and stability of the clusters, they will be compared for clinical interpretation.

Study burden and risks

The risk for adverse events due to participation in this study is minimal. Subjects will undergo measurements according to the standard protocols as used in daily clinical care. There is no direct benefit for patients. However, it might result in more personalized medicine and improved prognosis for asthma patients.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age >=18 year (Adult)
Confirmed asthma diagnosis by a health professional
Under treatment in secondary care for asthma
Using ICS on daily basis
At least one type 2 asthma characteristic present:
- High blood eosinophils
- High sputum eosinophils
- High fractional exhaled nitric oxide (FeNO)
- Allergen mediated asthma (allergic symptoms supported by at least one positive specific blood IgE test)

Exclusion criteria

Use of biologicals or prednisolone
Asthma exacerbation within 6 weeks before inclusion
Not able to perform lung function test or having a contraindication to do so
Current smoker or more than 10 pack-years
Has been tested positively for COVID-19 within last two months
Other respiratory diseases than asthma

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2021
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	31-05-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24616
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77049.100.21
OMON	NL-OMON24616