The 2CLASS study: Defining type 2 asthma phenotypes based on clinical, biological and functional parameters using cluster analysis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24616

Source
Nationaal Trial Register

Brief title
2CLASS

Health condition

Asthma

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: None

Intervention

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.

The main objective is to investigate the heterogeneity of type 2 asthma by identifying phenotypes by means of cluster analysis.

Asthma patients with at least one type 2 asthma characteristic that are under treatment in secondary care will be included. 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 objective

Several phenotypes can be defined within type 2 asthma

Study design

One

Contacts

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Eligibility criteria

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 non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-06-2021
Enrollment:	240
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51135
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9565
CCMO	NL77049.100.21
OMON	NL-OMON51135

Study results