Phenotyping and classifying of childhood and adult asthma exacerbations: towards future personalised treatment. An observational multicentre study.

Published: 21-02-2022
Last updated: 27-12-2024

The primary objective of the study is to determine the relationship between exacerbation treatment response at day 7 and the phenotypical characteristics of asthma exacerbations. Secondary objectives are 1) developing a prediction model based on...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON56464

Source
ToetsingOnline

Brief title
ExCluSie-F study

Condition

- Respiratory disorders NEC

Synonym
Asthma

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland

Source(s) of monetary or material Support: Astra Zeneca,Stichting O&O van Franciscus Gasthuis

Intervention

Keyword: Asthma exacerbation, Classification, Phenotype

Outcome measures

Primary outcome

Primary endpoint is the relation of phenotypical characteristics with treatment response at day 7, defined by 1) the physician - and patient rated global evaluation of treatment effectiveness (GETE) score 2) difference in Asthma Control Questionnaire 5 (ACQ-5) (> 0.5) 3) difference in handheld spirometry values like forced expiratory volume (FEV1 >= 10%). Treatment response will be classified as excellent, good, moderate or poor.

Secondary outcome

Secondary endpoints are 1) a prediction model for the treatment response of AAE 2) aetiology of the AAEs 3) blood and local respiratory parameters; microbiota composition; lipid metabolomics and volatile compounds composition at baseline and AAE

Study description

Background summary

Asthma is a heterogeneous inflammatory respiratory disease affecting 8 - 9% of the European population. Acute asthma exacerbation (AAE) is characterized as an acute worsening of symptoms and is treated inconsistently with steroids with or without antibiotics. In order to adjust and personalise exacerbation treatment, phenotyping and classifying of asthma exacerbations would be required. Therefore, we want to classify patients with AAEs phenotypically in relation to

the treatment response.

Study objective

The primary objective of the study is to determine the relationship between exacerbation treatment response at day 7 and the phenotypical characteristics of asthma exacerbations.

Secondary objectives are 1) developing a prediction model based on biomarkers and/or clinical data to predict the treatment response of AAEs 2) comparing the environmental, inflammatory, microbiological and lipid parameters of patients diagnosed with asthma between exacerbation phase and recovery (baseline)

Study design

A prospective cohort multicenter study.

Study burden and risks

Asthma patients will not have personal benefit from participating in this study. The low burden from participating in this study is in proportion with the potential value of this study for the total asthma population. The low burden for patients includes the venous punctures (2x), nasopharyngeal swabs (2x), performing daily questionnaires, spirometry, and FeNO measurements for a week.

Contacts

Public
Franciscus Gasthuis & Vlietland

Kleiweg 500
Rotterdam 3045PM
NL
Scientific
Franciscus Gasthuis & Vlietland

Kleiweg 500
Rotterdam 3045PM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients between 12 and 70 years old, diagnosed with asthma according to the GINA guidelines. If patients are doctor*s diagnosed with asthma based on clinical data, the further diagnostics will be performed to confirm the diagnosis after the AAE.
- Mild to severe asthma, treated according to GINA guidelines with medium - or high dose inhaled corticosteroids (with or without LABA) or treated with a low dose inhaled corticosteroids combined LABA or leukotriene - receptor antagonist.
- Asthma exacerbation, indication for systemic corticosteroids.
- Written personal and/or parental informed consent, prior to any study procedures.
- Eligibility and willingness to present during an asthma exacerbation at the outpatient clinic of the Study sites.
- Ability to use e - health applications.

Exclusion criteria

- Immunosuppressive maintenance medication (azithromycin, systemic corticosteroids maintenance therapy and other) or recently (< 6 weeks) discontinued these medications. (Desensitization therapy indicated for allergies can be included in the study)
- Maintenance medication or recently discontinued (< 6 weeks) anti-inflammatory biologicals.
- Other underlying active inflammatory or auto-immune diseases with systemic immunosuppressive medication, such as rheumatologic disease.

- Involvement in the planning and/or conduct of the study (applies to both investigator staff and/or staff at the study site)
- Pregnancy, because of the possible altered immunological status.
- Participation in an interventional study or randomised controlled trial.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-09-2022
Enrollment:	200
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	21-02-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-09-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	23-08-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-12-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL79257.100.21