Phenotyping and classifying of adult asthma exacerbations: towards future personalized treatment - A multicenter observational cohort study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON57364

Source
ToetsingOnline

Brief title
ExCluSie-F 2

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Asthma Attack, Asthma exacerabtion

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland

Source(s) of monetary or material Support: Longfonds

Intervention

Keyword: Asthma, Exacerbation, Prednisone, Treatment effect

Outcome measures

Primary outcome

The main study parameters are (1) the chosen treatment strategy (e.g. cumulative dose of prednisone and/or antibiotics), and (2) treatment effect measured on day 14. Treatment effect is determined on the need of additional AE treatments between day 0 and 14. Treatment effect is also measured by the physician and patient rated global evaluation of treatment effectiveness (GETE) score, difference in Asthma Control Questionnaire 5 (ACQ-5), difference in forced expiratory volume (FEV1) measured with handheld spirometry.

Secondary outcome

Secundary study parameters are (1) to measure effect treatment on FeNO, eosinophils an neutrophils (at day 0 and day 14), (2) to monitor the side effects of prednisone, (3) to measure asthma control and stress and emotional wellbeing (questionnaire) and its possible correlation with the (patient experienced) treatment effect, and (4) to observe the chance on AAE relapse within 6 weeks.

Study description

Background summary

Asthma is a heterogeneous inflammatory airway disease affecting 8-9% of the European population and is the most common chronic disease among children. Moderate-to-severe asthma exacerbations (AE) are treated with bronchodilators, oral corticosteroids (OCS) and/or antibiotics, with little attention paid to the underlying asthma heterogeneity in type of inflammation and exacerbation triggers. Although precision medicine and targeted therapies, such as biologicals, are practiced in the maintenance treatment of severe asthma, this does not (yet) apply to AE management. For AE treatment to move forward, tools are urgently needed to more accurately phenotype and classify AE. An improved understanding of inflammatory pathways, identification of a rapid discriminative marker set, and exploration of precision medicine strategies are crucial for ensuring appropriate use of anti-inflammatory drugs and antibiotics in a personalized fashion. This is expected to improve clinical outcomes and reduce adverse events and costs.

Study objective

The main objective of this study is to observe current AE treatment strategies and the treatment response of these strategies after 2 weeks in several hospitals. Secondary objectives are (1) to measure effect treatment on FeNO, eosinophils and neutrophils (at day 0 and day 14), (2) to monitor the side effects of prednisone, (3) to measure stress and emotional wellbeing (questionnaire) and its possible correlation with the (patient experienced) treatment effect, and (4) to observe the chance on AE relapse within 6 weeks.

Study design

The study is a multicenter prospective study and consist of 2 phases. In the 1st phase, we will perform an observational cohort study in regional hospitals. This cohort also serves as a *control* cohort in the phase 2 stepped wedge cluster-randomized trial investigating the overall performance of the AE treatment algorithm on clinical outcomes and medication use in AE. For phase 2 separate METC approval will be requested.

Study burden and risks

Participating patients will not have personal benefit from participating in this study. The low burden from participating in this study is proportional with the potential value for the total asthma population. The low burden for patients includes venous puncture (on day 0 and day 14), questionnaires (on day 0,, day 7, day 14 and day 42), spirometry and FeNO measurements (on day 0 and day 14).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult (16+) patient diagnosed with asthma according to the GINA guidelines.

Moderate 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 informed consent, prior to any study procedures.

Eligibility and willingness to present during an asthma exacerbation at the

outpatient clinic facility of the study sites.

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) biologicals used for the treatment of asthma.

Other underlying inflammatory or auto-immune diseases, 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.

Already started with systemic corticosteroids course before possible inclusion.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	147
Type:	Anticipated

Ethics review

Approved WMO Date:	12-03-2025
Application type:	First submission
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	NL87351.100.24