Early detection of the effectiveness of treatment with biologicals in patients with severe asthma using fluctuation analysis of biomarkers

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To investigate the fluctuation patterns of different pulmonary parameters in patients with severe asthma, before and after starting a treatment with biologics, using daily measurements with the Respicorder device.

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

Summary

ID

NL-OMON56494

Source
ToetsingOnline

Brief title
FABLE (Fluctuation analysis in asthma and biologics use)

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma, Asthma Bronchiale

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Eureka network

Intervention

Keyword: Asthma, Biologics, Biomarkers, Fluctuation Analysis

Outcome measures

Primary outcome

The Respicorder device measures standard spirometry (FEV1, FVC), IOS parameters and FeNO, which will be used for fluctuation analysis. The Asthma Control Questionnaire (ACQ) and Asthma Quality of Life Questionnaire (AQLQ) will be used to quantify asthma status. Patients will be evaluated by their treating clinician after 4 and 6 months of treatment with a biological. The outcome will be linked to the fluctuation patterns, such that can be evaluated whether these patterns can be used to predict a successful treatment with a biologic.

Secondary outcome

Spirometry, IOS and FeNO measurements with standard devices as done in standard care in the hospital will be used to compare with the Respicorder measurements. Subjects will also be asked about their experience with the Respicorder.

Study description

Background summary

Treatment of patients with severe asthma has taken a new avenue with the introduction of biologics. Currently, treatment success with biologics may be around 75% and is determined by assessing various biomarkers after 4 to 6 months of treatment. At a stable state, biological processes dynamically fluctuate within certain borders, which differ between asthma and healthy controls. By exposure to the common cold virus, we have shown that destabilizing the condition of asthma patients and healthy controls directly but temporarily changes the fluctuation patterns of biological processes. We

propose that treatment success also changes fluctuation patterns, and that this occurs relatively fast after treatment is started. By daily measurements of spirometry, fraction of exhaled nitric oxide (FeNO) and impulse oscillometry (IOS), using the Respicorder device, we expect to determine the effect of treatment at an early stage and limit prolonged treatment of patients with a non-effective biologic, and the very high costs of these biologics.

Study objective

To investigate the fluctuation patterns of different pulmonary parameters in patients with severe asthma, before and after starting a treatment with biologics, using daily measurements with the Respicorder device.

Study design

The study design is an observational cohort study that will include patients that are scheduled for an intervention with biologic treatment in standard care. Patients will receive their standard treatment and will perform some extra measurements during their regular visits and they will perform measurements with the Respicorder device twice a day at home.

Study burden and risks

The risk for adverse events due to participation in this study is minimal. The daily additional measurements with the Respicorder device can be a burden to patients. The Respicorder measurements take about 5 minutes, which we consider as an acceptable burden given the expected impact of the study. Subjects will also be subjected to measurements according to the standard protocol in clinical care.
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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Severe asthma based on the definition by the 2022 GINA guidelines.
• Will start treatment with a biological
• 18-60 years old
• Subject should be willing and able to perform the lung function tests and other study-related procedures and comply with study protocol requirements.
• Apart from their asthma, subjects should be generally healthy with no history of a clinically relevant medical condition that in the opinion of the investigator might interfere with successful study conduct and no clinically relevant abnormalities on medical history.
• Subjects should provide a signed and dated informed consent

Exclusion criteria

• Has been tested positively for COVID-19 in the past month or has not fully recovered from an earlier COVID-19 infection (e.g. post-covid syndrome) • Has been treated with oral corticosteroids as high-dose therapy in the 6 weeks before visit 1. • Has been treated with another biologic within 3 months before start treatment with new biological (e.g. 2 months before the start of the study participation) • Not able to perform spirometry/IOS/FeNO tests correctly • Not able to handle Respicorder well • Subject is a current smoker/vaper, uses recreational drugs, or has >10 packyears • Subject is anticipated not to comply with study protocol or other aspects of the study (at the discretion of the investigator) • Participation to the study is not medically responsible according to the study physician and/or principle investigator • Inability to read and/or understand the Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2025
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Respicorder
Registration:	No

Ethics review

Approved WMO

Date:	03-01-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT06024707
CCMO	NL83718.018.23