Impact of asthma on daily life: an international qualitative study to understand the impact of acute worsening of asthma on daily life

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1. To evaluate the impact of acute worsening events on daily lives of patients with asthma2. To identify and explain the acute worsening associated behaviours, including the underlying reasons for not consulting a healthcare professional.3. To...

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

Summary

ID

NL-OMON56536

Source
ToetsingOnline

Brief title
Impact of asthma

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Astra Zeneca

Source(s) of monetary or material Support: AstraZeneca

Intervention

Keyword: activities of daily living, asthma, qualitative research, symptoms

Outcome measures

Primary outcome

Not applicable

Secondary outcome

Not applicable

Study description

Background summary

Most randomised controlled trials (RCTs) studying the efficacy of a new treatment for asthma define the primary outcome as occurrence of a severe exacerbation for which the patient gets systemic corticosteroids prescribed. However, patient diaries applied in RCTs have shown that it happens frequently that periods of worsening symptoms are not reported to healthcare professionals and are therefore not recorded as exacerbations in healthcare systems. The clinical importance and impact of these unreported acute worsening events (AWEs) on patients with asthma is largely unknown. Interventions at the intermediary stage of acute worsening may mitigate progression to severe exacerbation that requires more intense treatment including hospitalisations In a post-hoc analysis of RCTs conducted in patients with asthma, various combinations of predefined threshold values for peak expiratory flow, reliever medication use, and symptoms were tested to objectively define acute worsening events. A composite endpoint (CompEx Asthma) was defined as the occurrence of such an acute worsening event or a severe exacerbation. The performance of this composite endpoint was tested in 7 trials and at the end of follow-up, the proportion of patients experiencing a CompEx Asthma event increased almost 3-fold versus severe exacerbations alone. Furthermore, the study showed that CompEx Asthma can be used as a novel endpoint in RCTs as it consistently reflected the treatment effect on severe asthma exacerbations. Extending the definition of an exacerbation to include AWEs will encompass differences in help-seeking behaviour and increase generalisability across different healthcare systems. In addition, it will increase event rates and reduce the required sample size.

For this, it is important to increase knowledge of the clinical importance of unreported AWE*s and to better understand why patients do not consult a healthcare professional for worsening of their condition.

Study objective

1. To evaluate the impact of acute worsening events on daily lives of patients with asthma
2. To identify and explain the acute worsening associated behaviours, including the underlying reasons for not consulting a healthcare professional.
3. To collect patient-reported outcome (PRO) data for evaluation of psychometric properties of the CompEx items.

Study design

A qualitative study will be conducted in five countries (The Netherlands, Australia, Portugal, United Kingdom (UK), United States of America (US)). Participants will be recruited through pharmacies and healthcare professionals. After a baseline period of 1 week, they will be followed up for 12 weeks to monitor the occurrence of an acute worsening event (AWE). A previously established algorithm (CompEx Asthma) will be used to define these events based on diary records. Participants who have an AWE will be selected for two interviews. The initial interview will be held at 3±2 days after the occurrence of an event. A second interview will be scheduled 4 weeks ± 4 days after the first interview when most participants are expected to have recovered from the event. In the case of an AWE, participants will be followed up until the date of the second interview (for a maximum of 18 weeks), to capture the participant's state during the second interview.
A topic list and an interview guide will be used as a framework for the interviews. To avoid influencing the behaviour of participants, they will not be informed that the AWE was a trigger for the first interview.

Study burden and risks

Participants will twice a day (morning and evening) fill in an online diary and perform a peak flow measurement. This will take approximately 10 minutes every time. The peak flow measurement is not painful, but does take effort. We estimate that 18% of the participants will be invited for two online interviews of 30 minutes.

There are no risks associated to taking part in this study.

There are no direct benefits for individual participants. However, if the study indicates that the new clinical outcome based on a change is symptoms performs equally well as the standard outcome, this could strongly reduce the burden for future research participants as the novel outcome has a three times higher

incidence.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

>=18 years old
Documented diagnosis of asthma for >=12 months
Documented history of >=1 severe exacerbation in the last 12 months
Symptomatic (Asthma Control Questionnaire-6 score >= 1.5)
Use of inhaled corticosteroid at a stable dose for >=3 months prior to enrolment
BMI 18-32 kg/m2

Exclusion criteria

Recent severe asthma exacerbation (within 6 weeks)
Clinically important other pulmonary disease, including COPD

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-02-2024
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	09-02-2024
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL85661.056.23